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S. Hrg. 109–846

ENSURING EARLY DIAGNOSIS AND ACCESS TO TREATMENT FOR HIV/AIDS: CAN FEDERAL RESOURCES BE MORE EFFECTIVELY TARGETED?

HEARING

BEFORE THE

FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, AND INTERNATIONAL SECURITY SUBCOMMITTEE

OF THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

APRIL 26, 2006

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ENSURING EARLY DIAGNOSIS AND ACCESS TO TREATMENT FOR HIV/AIDS: CAN FEDERAL RESOURCES BE MORE EFFECTIVELY TARGETED?

WEDNESDAY, APRIL 26, 2006

U.S. SENATE,
FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, AND INTERNATIONAL SECURITY SUBCOMMITTEE,
OF THE COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:27 p.m., in room SD–342, Dirksen Senate Office Building, Hon. Tom Coburn, Chairman of the Subcommittee, presiding.

Present: Senators Coburn and Carper.

OPENING STATEMENT OF SENATOR COBURN

Senator COBURN. Thank you. We are going to start early. We are going to have a vote here in a few minutes which will mean we will have to interrupt the hearing, so I am going to go on and start, if I may.

I want to welcome all of our witnesses today. I want to thank you for the timeliness of your testimony and thank you for taking the time to be here.

Today's hearing examines domestic efforts to promote early diagnosis of HIV infection and ensure access to AIDS treatment.

It has been nearly 25 years since the first cases of what would become known as AIDS were recognized. As a physician during much of this time period, I experienced the heartbreak of watching some of my patients, including mothers and children, succumb to this mysterious and incurable illness in the early days of the epidemic when effective treatments had not yet been developed.

Even today, with the availability of revolutionary anti-retroviral treatments that have transformed a disease that was a death sentence into a manageable disease for many, it is still heartbreaking to deliver an HIV diagnosis to a patient and agonize with each one to determine how they can afford these life saving, yet extremely expensive, medications.

As a physician, I believe it is essential that if we are to end this epidemic, we must make every effort to promote early diagnosis and ensure access to treatment for all those who are infected. We must also empower those who are infected and those who are not infected to prevent HIV from taking another life. This may require

rethinking and reevaluating past and present policies and reconsidering ideas that have long ago been abandoned or even demonized.

It is no secret that I have had many differences with some within the AIDS community, Federal health agencies, and even with the drug companies that produce the miraculous AIDS drugs that now many take for granted regarding how we could best address this disease. But we must not let our differences of opinions allow us to make enemies of those with different viewpoints, for we all hold the same common goal: Ending AIDS and the same common enemy, HIV.

So many of the medical advances that my patients and those affected by HIV around the world benefit from today are the result of activists who forced the government to act on this epidemic when so many preferred to look away because they disapproved of the behaviors that were associated with this disease.

Unfortunately, so much of how we have all reacted to the AIDS epidemic has been based on fear. Lack of knowledge led to fear. Fear led to discrimination and stigma. Discrimination and stigma led to fear. And fears became the basis of our response to HIV/AIDS. The results have been tragic.

Consider that the U.S. Government spends more than $20 billion a year on HIV/AIDS prevention, care, and research annually, yet more than one million Americans are now living with HIV/AIDS. Up to 59 percent of those Americans are not in regular care. More than 40,000 Americans become newly infected with HIV every year. It has not changed over the last 6 to 7 years, and this number has actually been unchanging for over a decade, as that chart will show.[1] There are some estimates that it is as high as 60,000 new cases a year. The fact that we don't know for sure tells us we have a problem.

More than a quarter of those who are infected do not know they are infected. Hundreds of patients are on waiting lists for AIDS drugs, and more than half a million Americans have already died from this disease. As many as 45 percent of persons testing positive for HIV received their first positive test result less than a year before the AIDS was diagnosed. With an average of 10 years between HIV infection and an AIDS diagnosis, this suggests that people are living with HIV for many years before they are aware of their infection and may be unknowingly spreading the virus to others.

To address these shortcomings, fear must be replaced with hope. We have the knowledge, the resources, and the commitment to provide hope to every American who is living with HIV/AIDS. But to do so, we must update our policies to ensure that all of those living with HIV have access to the hope that treatment can provide.

This means we must also remove the barriers to testing. Fear-based policies continue to serve as deterrents to testing and diagnosis and deny the benefits of those miraculous AIDS drugs that the early activists fought so hard to make available to thousands of Americans today, often until it is far too late to prevent the inevitable.

One example of the hope that can result from eliminating barriers to testing is the great success that has resulted from the baby

[1] The chart referred to appears in the Appendix on page 132.

AIDS laws in New York and Connecticut that require every newborn to be tested for HIV antibodies and treatment provided to affected mothers and infants.

New York passed a law requiring HIV testing of all newborns in 1996. According to data we received just this week, the results of this law have been dramatic.[1] The proportion of all pregnant women being aware of their HIV status at delivery has increased from 64 percent in 1997 to 95 percent in 2004. The number of HIV-infected infants in New York dropped from more than 500 a year to 8 in 2003. Furthermore, mothers and impacted infants are receiving care.

Connecticut passed a similar law in 1999 requiring that newborns be tested for HIV antibodies if their mother's HIV status was unknown. Prior to the law, only 28 percent of pregnant women were documented as being tested for HIV.[2] Prenatal testing rates for other diseases were over 90 percent, which demonstrates how the unusual counseling regulations for HIV testing discouraged testing. After the law was enacted, this number of pregnant women being tested for HIV jumped to 90 percent. In the year that the law passed, 70 HIV-exposed newborns were born with five infants infected with the virus. Since that time, over 300 HIV-exposed infants have been born with only five infants becoming infected. The last baby infected with HIV to be recorded in the State was in 2001, meaning Connecticut's laws essentially eliminated baby AIDS.

The success of these laws are rare victories in our battles against HIV and AIDS.

The Government Accountability Office (GAO) today releases its second report this year that examines some of the issues involved in providing access to treatment and early intervention. The report reminds us of facts that we already know, such as most new HIV infections originate from HIV-infected persons not yet aware of their status. This emphasizes the need to identify HIV-infected persons and link them with appropriate services as soon as possible.

It raises other issues of concern, such as ADAPs with waiting lists may not represent all eligible individuals who are not being served. And it points to opportunities where policy makers can do a better job to maximize the impact of the tens of billions of dollars that we are directing every year towards our HIV/AIDS efforts.

Coincidentally, GAO's reports come at a time when Congress is faced with reauthorization of the Ryan White CARE Act, which is the largest HIV/AIDS-specific Federal care program. While the program's authorization expired 6 months ago, efforts are currently being made to renew the program, and I know of at least one bill that has been introduced in both the House of Representatives and the Senate that would do so taking account of many of GAO's findings as well as the issues I have outlined and others that we will explore today.

I look forward to hearing from our witnesses today, who include Dr. Marcia Crosse, Director of Government Accountability Office's Public Health and Military Health Care Issues; Dr. Deborah

[1] The chart referred to appears in the Appendix on page 131.
[2] The charts referred to appear in the Appendix on pages 129–130.

Hopson, Associate Administrator of the Health Resources and Services Administration, HIV/AIDS Bureau; Dr. Kevin Fenton, Director of the National Center for HIV, STD, and TB Prevention at the Centers for Disease Control and Prevention; Ms. Beth Scalco, Director, HIV/AIDS Program, Louisiana Office of Public Health; and Michael Weinstein, President of the AIDS Healthcare Foundation, the Nation's largest provider of HIV/AIDS medical care.

Prior to you coming in, Senator Carper, I announced that we were going to have a vote. I will go vote if you will do youre opening statement. I will be right back and we will try to keep things going.

Senator CARPER. OK, sounds good.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER [presiding]. Thanks, Mr. Chairman, and before you leave, let me just say that the Chairman of the Subcommittee has been very involved in these issues for some time and is one of the co-authors of the last reauthorization. I know he has been very much involved in our efforts to reauthorize the Ryan White CARE Act this time, as well.

Thank you for joining us. We look forward to your testimony and to the opportunity to ask some questions of you, and our second panel, as well.

The Ryan White CARE Act was first enacted, I believe in 1990. I was still in the House of Representatives at the time. Since then, we have made great progress, both in combatting the stigma that was once associated with the disease, but I think also in combatting the disease itself. We still have a long ways to go, but the CARE Act has been, I think, one of the chief Federal programs, at least, in the fight against HIV and AIDS.

I think we can all agree that our goal in examining the Ryan White Act today is to ensure that Americans living with HIV/AIDS can get needed care and needed services. The Ryan White program is working to do that, at least that is what I am told, for over 500,000 people each year. The program provides not only vital prescription drugs, but also needed support services to help patients stay on those drugs and adhere to complex drug regimens.

In my State of Delaware, we have done, we think, a good job of providing needed health services to those with HIV and AIDS. We can always do better. Everything we do, we can do better, and that includes here. But we have made quality health care a priority and are fortunate to be able to offer what we think is a generous Medicaid program, a very generous AIDS drug assistance program, and high-quality Ryan White services.

The witnesses that are here today before us, this panel and our next panel, will discuss a number of issues, largely focusing on the AIDS drug assistance program, on prevention and testing efforts, and on notification efforts. However, they will also be addressing a number of issues pertaining to the Ryan White authorization as a whole. At least, that is what I am told.

I understand that the Senate HELP Committee and the House Energy and Commerce Committee are working together in a bipartisan way to come to agreement on the Ryan White Reauthoriza-

tion Act, and I hear they are making significant progress and I hope that the authorization can be completed this year.

As we consider reauthorization of this program, I think it is important that we keep in mind that the program, on the whole, is working. We have lengthened the time from HIV infection to the onset of AIDS, which is a good thing. People with HIV and AIDS are living longer and living healthier. That is obviously a good thing. Of course, we can, as I said earlier, do more to strengthen the program, and we now face new challenges as the face of the disease itself evolves. I think, for the most part, we have done a good job, a commendable job.

One of the goals of reauthorization should be to ensure that we can get the most out of our Federal investment in this program. We should ensure that the distribution of funding to States and cities under the CARE Act both supports the existing treatment infrastructure that we have built up over the last several years and also ensures that we address discrepancies in funding where they are present. We should ensure that the Ryan White dollars are spent in a smart way and that they are spent as a payer of last resort. We should also ensure that any unused funds are reinvested in the program in some way.

I hope that the issues that are brought up before us today can inform the upcoming debate on reauthorization. Ryan White has always been seen as a bipartisan issue and I am hopeful that this year, the Congress will continue that tradition and that we can work together with the House to produce a bipartisan reauthorization package to send to the President for his signature.

I think with that having been said, I am going to recess the Congress, go and vote myself, and I suspect that the Chairman will be back very shortly and begin your testimony. So I would just ask that we stand in recess for a few moments until the return of the Chairman and I will see you all then. Thank you.

[Recess.]

Senator COBURN [presiding]. Let me introduce, if I may, our first panel. I would ask our panel members to limit their testimony to 5 minutes. We have read your testimony. Then we will have questions afterward.

Dr. Kevin Fenton is Director of the National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention. He joined CDC in January 2005 as Chief of the National Syphilis Elimination Effort, leading a revitalization of this program to end the sustained transmission of syphilis in the United States. Prior to his work at CDC, Dr. Fenton was the Director of the HIV and Sexually Transmitted Infections Department of the United Kingdom's Health Promotion Agency.

Dr. Deborah Parham Hopson is the Associate Administrator for HIV/AIDS in the U.S. Department of Health and Human Services' Health Resources and Services Administration. Dr. Hopson was appointed Associate Administrator for HIV/AIDS at HRSA on July 29, 2002. As Associate Administrator for the AIDS Bureau, Dr. Hopson is responsible for directing the Ryan White Comprehensive AIDS Resources Emergency Care Act Program, which provides medical care, treatment, referrals, and social services to people living with and affected by HIV/AIDS throughout the United States.

She administers a budget of $2.02 billion that funds services for some 530,000 individuals each year.

Dr. Marcia Crosse is Director for the Health Care Group at the Government Accountability Office. She has been responsible for overseeing multiple projects in the areas of biomedical research, bioterrorism, disease surveillance, HIV/AIDS, medical product safety, organ transplantation, and pharmaceutical regulation. She has been employed at GAO since 1985.

I want to thank each of you again for being here, and I want to express publicly how much I depend on GAO, what a great functioning component of the U.S. Government they are, and how valuable they are to us as Members of Congress in being able to do our work.

Dr. Fenton, I will recognize you first and then we will go to Dr. Hopson and then to Dr. Crosse. Welcome.

TESTIMONY OF KEVIN FENTON, M.D.,[1] DIRECTOR, NATIONAL CENTER FOR HIV, STD, AND TB PREVENTION, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. FENTON. Good afternoon. Thank you. Good afternoon, Mr. Chairman. My name is Kevin Fenton and I am the Director of the National Center for HIV, STD, and TB Prevention at the Centers for Disease Control and Prevention. Thank you for the opportunity to discuss CDC's progress in reducing barriers to HIV testing and improving opportunities for early diagnosis and linkage to care.

Twenty-five years ago, the first cases of HIV were reported in the United States. Although the struggle to prevent new infections is not over, we have made substantial progress and achieved major successes. For instance, the dramatic decrease in mother-to-child or perinatal HIV transmission is one of the great success stories of HIV prevention. We have also seen declines in the number of HIV and AIDS cases attributed to injecting drug use.

Despite such major successes, HIV infection and AIDS remain a leading cause of illness and death in the United States. The numbers are sobering. CDC estimates that currently, 1 to 1.2 million people in the United States are infected with HIV, and of these, roughly a quarter are undiagnosed and at high risk of transmitting HIV. This undiagnosed group is of great concern to us because they are not able to take advantage of medical treatment and because we believe that transmission by people who are unaware that they are HIV positive account for more than half of new HIV infections every year.

Currently, CDC has a number of efforts underway to encourage early diagnosis of HIV infection. In 2003, CDC launched the Advancing HIV Prevention Initiative, or AHP, which reinforces CDC's evidence-based approach that routine HIV testing implemented in a variety of settings will reduce barriers to HIV testing, improve opportunities for early diagnosis and linkage to prevention and care, and help reduce the number of new infections.

CDC also encourages its funded partners to take HIV testing out into the community by using rapid tests in non-traditional settings

[1] The prepared statement of Dr. Fenton appears in the Appendix on page 31.

and in health care settings that provide episodic care. In addition, CDC is currently updating guidelines for testing in health care settings, making HIV testing more routine.

Finally, the President's 2007 budget contains an increase in funding aimed at increasing the number of people who know their HIV serostatus through promoting rapid testing in areas of high HIV incidence.

I would like to highlight one AHP demonstration project that we are particularly encouraged about. This project used social network strategies to reach persons at high risk of HIV infection in communities of color and demonstrated the feasibility of using these social networks to encourage HIV counseling, testing, and referral services. This strategy has proved to be very successful in reaching persons with undiagnosed HIV infection.

In addition to reducing barriers to HIV testing and increasing the opportunity for early diagnosis, CDC is proposing to revise our guidelines for HIV testing of adults, adolescents, and pregnant women in health care settings. The revised guidelines will focus on increasing routine HIV screening of patients in health care settings, fostering the earlier detection of HIV infection, identifying and counseling persons with unrecognized HIV infection, and linking them to clinical and preventive services and further reducing perinatal transmission of HIV in the United States.

Detecting HIV infection earlier through HIV screening has been shown to be cost effective, even in settings of low prevalence. The new guidelines will recommend routine or opt-out HIV screening in health care settings and are intended for providers in all health care settings. The guidelines do not modify existing guidelines for HIV counseling, testing, and referral for high-risk persons who seek HIV testing in non-clinical settings.

As you know, to further support the goal of diagnosing HIV infections earlier and increasing access to care, the President's 2007 budget includes an increase of $93 million for CDC HIV prevention programs. Three major testing components are included: Testing in health care and non-clinical settings, in jails, and with injecting drug users. CDC will work collaboratively with other HHS agencies in these efforts. We anticipate testing more than three million persons and identifying over 46,000 infections.

In closing, over the past 25 years, our Nation has made progress in preventing morbidity and mortality related to HIV. CDC remains committed to helping people live longer, healthier lives by preventing new HIV infections and protecting the health of those already infected.

Thank you again for this opportunity and I look forward to answering any questions.

Senator COBURN. Thank you, Dr. Fenton. Dr. Hopson.

TESTIMONY OF DEBORAH PARHAM HOPSON,[1] ASSOCIATE ADMINISTRATOR, HIV/AIDS BUREAU, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. HOPSON. Mr. Chairman, thank you for the opportunity to meet with you today on behalf of the Health Resources and Services Administration. Last year, I testified before the Subcommittee regarding the domestic HIV/AIDS care programs and I am happy to be here today to discuss ways to ensure early diagnosis and improve access to treatment for Americans living with HIV and AIDS. I certainly appreciate your continuing support for the Ryan White CARE Act programs.

The Ryan White CARE Act is the centerpiece of our domestic response to care and treatment for low-income, uninsured, and under-insured individuals living with HIV/AIDS. Currently funded at over $2 billion, it provides primary health care, live-saving medications, and support services to individuals who lack health insurance and financial resources to provide adequate health care for themselves.

As you noted, the authorization of the Ryan White CARE Act expired 6 months ago. President Bush in his State of the Union Address stressed the importance of this program and asked Congress to reform and reauthorize the Ryan White CARE Act and provide new funding to States so that we can end the waiting list for AIDS medicines in America.

Since its last reauthorization, we have been able to provide antiretroviral treatment, primary care, and support services to over half a million people annually in the United States, Puerto Rico, Guam, the Virgin Islands, and eligible U.S. territories in the Pacific. In 2004, an estimated 65 percent of these individuals were racial minorities, 33 percent were women, and 87 percent were either uninsured or received public health benefits. The Ryan White CARE Act programs have provided important benefits to these populations.

Overall, AIDS mortality is down and lives have been extended through HIV medications purchased through the AIDS Drug Assistance Program, also known as ADAP. Pregnant HIV-positive women have been provided with care that has allowed them to give birth to children free from HIV infection, and thousands have received support services that have allowed them to access and remain in health care.

Although we are making progress in providing services to people living with HIV, the epidemic continues and will be in need of our attention for some time to come. The President and Secretary understand the dynamics and severity of the epidemic and they are committed to ensuring the Department's HIV/AIDS programs are as effective as possible in preventing infection and treating those who become infected.

We have recognized that as essential as the Ryan White CARE Act has been to serve Americans with HIV and AIDS, it is in need of revitalization to safeguard its critical mission. Despite record levels of funding, we continue to face waiting lists for life-saving

[1] The prepared statement of Ms. Hopson appears in the Appendix on page 46.

funds through the ADAP and there are marked disparities in access to quality medical treatment across the country. As minority populations are increasing and disproportionately impacted by HIV/AIDS, changes to the existing systems of care designed for an earlier epidemic are increasingly urgent.

Each year, CARE Act programs, primarily through grants to States, metropolitan areas, providers, and educators, we reach an estimated 571,000 people. Since AIDS was first recognized, the pattern and treatment of HIV disease has shifted. We now strive to manage HIV/AIDS as a chronic disease. Early diagnosis and improved access to HIV care and treatment are key to what the CARE Act stands for.

The CARE Act programs are successful at counseling and testing. More than 800,000 HIV tests were administered in CARE Act sites. And the important thing to note is over 85 percent of the people tested in CARE Act sites returned for their results. We think that this is because the CARE Act sites are not only testing sites, but they are primary care delivery sites, as well.

Going forward, we take great pride in the advances of HIV/AIDS care and treatment that have been made by the CARE Act programs over the past 16 years. However, we are humbled by the significant challenges that remain for people living with HIV/AIDS who have nowhere else to go for care in an age of increasing HIV/AIDS prevalence, increasing health care costs, and a growing burden of HIV among the uninsured and under-insured.

The Administration has emphasized five key principles for reauthorization of the CARE Act: Serve the neediest first; focus on life-saving and life-extending services; increase prevention efforts; increase accountability; and increase flexibility.

The President has made fighting the spread of AIDS a top priority of his Administration and he will continue to work with Congress to encourage prevention and provide appropriate care and treatment to those suffering from the disease.

Today, people with HIV/AIDS are living longer, healthier lives, in part because of the CARE Act. In order to make this legislation more responsive in the future, the Administration urges Congress to take into account the above-stated principles in the reauthorization of the CARE Act.

Thank you for the opportunity to discuss the Ryan White CARE Act today and for your dedication and interest in this important piece of legislation.

Senator COBURN. Thank you, Dr. Hopson. Dr. Crosse.

TESTIMONY OF MARCIA CROSSE,[1] DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. CROSSE. Mr. Chairman, I am pleased to be here today to discuss the AIDS Drug Assistance Programs, or ADAPs, that receive funds under the Ryan White CARE Act and to provide a summary of our report that we are releasing today, prepared at your and others' request. The report discusses ADAP's program design, their funding sources, and drug purchasing. It also discusses our examination of State prenatal HIV testing and perinatal HIV trans-

[1] The prepared statement of Ms. Crosse appears in the Appendix on page 55.

mission rates and State approaches to identifying and notifying partners of HIV-infected individuals.

Despite progress in drug treatments and the reduction of AIDS mortality in the United States, challenges remain concerning the availability of these drugs for individuals with HIV or AIDS. Because of the variation in program criteria, an individual eligible for ADAP services in one State may not be eligible for or receive the same ADAP services in another. ADAP income ceilings for individuals, program enrollment caps, and drug formularies vary considerably among ADAPs.

For example, each ADAP determines a maximum income level or income ceiling as a criterion for an individual's eligibility for enrollment. ADAPs reported income ceilings that range from 125 percent of the Federal poverty level in North Carolina to 556 percent in Massachusetts. Sixteen ADAPs reported that they had limits on the assets that individuals enrolled in the program are allowed to have. Twelve ADAPs reported having caps on program enrollment or on amounts expended per individual. And the total number of drugs ADAPs included on their formularies ranged from 20 in Colorado to 1,000 in Massachusetts, New Hampshire, and New Jersey.

In order to make maximum use of the funding they receive, ADAPs are expected to secure the best prices available for the drugs on their formularies. ADAPs may, but are not required to purchase their drugs through the 340B Federal drug pricing program, under which drug manufacturers provide discounts on certain drugs. HRSA has identified the 340B prices as a measure of ADAPs' economical use of grant funds, but HHS does not disclose 340B prices to the ADAPs.

We found that some ADAPs reported prices that were higher than the 340B prices for selected HIV/AIDS drugs. However, these reported prices may not have reflected any rebates ADAPs eventually received. While HRSA is responsible for monitoring whether ADAPs obtain the best prices available for drugs, it does not routinely compare the drug prices ADAPs report to the 340B prices, and without the final ADAP rebate amount on a drug purchase, HRSA cannot determine whether the final drug prices paid were at or below the 340B price.

We are recommending that HRSA require ADAPs to report the final prices they paid for drugs, net of any rebates, and that HRSA routinely determine whether these prices are at or below the 340B prices.

Turning to approaches to reduce the spread of HIV, all 50 States, the District of Columbia, and Puerto Rico have policies or have enacted laws regarding HIV testing of pregnant women to help reduce the transmission of HIV to newborns. However, among the eight States we examined, three States followed CDC's recommendations to routinely include HIV tests in standard prenatal testing while allowing a woman to refuse to be tested for HIV. The other five States require that a woman specifically consent to an HIV test, usually in writing, before the test can be performed. But two of these States, as you noted, Connecticut and New York, have mandatory newborn testing if the mother has refused an HIV test. Six of the eight States report that the number of HIV-positive newborns has declined, however, in a positive development.

Among other efforts to reduce the transmission of HIV, States used various approaches in eliciting information from known HIV-infected individuals about their sexual partners. But the participation of these individuals varies and not all partners can be reached to be notified. For example, CDC data showed that States interviewed between 46 percent and 100 percent of known HIV-infected individuals to elicit the identities of their partners and were able to notify between 42 percent and 83 percent of those partners that they had been exposed to HIV.

Further, in the 12 States we examined, 10 have statutory or regulatory provisions that require or permit the notification of partners, including spouses, without the consent of the known HIV-infected individual. However, in the remaining two States, Massachusetts and Minnesota, public health officials or the health department may notify partners, including spouses, only with the consent of the HIV-infected individual.

Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions you or other Members of the Subcommittee may have. Thank you.

Senator COBURN. Thank you, Dr. Crosse.

Dr. Fenton, I am going to start with you, if I may. Four years ago, Dr. Gerberding stated in her first speech as Director of CDC that 40,000 or more new HIV infections occur every year in the United States and it was unacceptable and our goal is to substantially reduce and ultimately prevent. If you look at that chart [1] and the fact that CDC now admits at least 40,000 new infections every year, which has not declined, what is the explanation for that?

Dr. FENTON. In reviewing that chart and in assessing our successes of our prevention interventions, I think there are two key questions that we need to ask ourselves. First, are we doing the right prevention interventions or do we have effective interventions and are we delivering them at the right level to have the necessary impact on our HIV epidemic? Or, second, as the epidemic is evolving, are we actually targeting our prevention interventions in the right areas for the right communities at risk?

CDC has a program of continually evaluating the effectiveness of our prevention programs. Over the past decade, we have been involved in monitoring the outcomes of our prevention activities and using our surveillance data to evaluate the effectiveness of our prevention interventions. We have systematically developed effective behavioral interventions and we have embarked upon a program of diffusing these effective interventions to communities and individuals at high risk of acquiring HIV.

We have also used core prevention indicators to evaluate the effectiveness of programs at the local level. Program consultants are required to interview our grantees to ensure that local implementation of our prevention programs are being done as anticipated.

Senator COBURN. Let me ask it in a little different way. We are going to spend over $20 billion this year in this country on domestic HIV/AIDS and we are climbing every year as we work on this very difficult problem. When are we going to see a decline in the new infections? Maybe we are not having more new infections,

[1] The chart referred to appears in the Appendix on page 132.

maybe we are diagnosing more that were in the resilient population. That may be the answer. But if you were an average American out there paying their taxes and—$18 billion to $20 billion, we started out very low and through the great work of AIDS activists, we are where we are today, when are we going to see that go this way? And this opinion, you are not going to be held to this. Just give us an opinion. [Laughter.]

I have got 4 more years here. I promise I won't hold you to it.

Dr. FENTON. I am not in a position to say exactly when we are going to be seeing a decline or a change in the epidemic curve, but I do know that we have had successes in preventing HIV transmission in some areas. We are beginning to see declines in new HIV diagnoses among injecting drug users. And earlier in my testimony, I mentioned the declines and the successes in perinatal HIV.

Senator COBURN. Right.

Dr. FENTON. More recently, our surveillance data is suggesting that we are seeing reductions in new diagnoses among African-American women. So taken as a whole, it may be very difficult to predict exactly when we will see declines in new diagnoses, but we are seeing successes. I think the key is actually identifying what elements of our—why are we seeing the successes——

Senator COBURN. What is working and what isn't?

Dr. FENTON [continuing]. And ensure that we either extend these and continue to implement these nationally.

Senator COBURN. Fifteen months ago, CDC unveiled its Advancing HIV Prevention Initiative. How many States have enacted the recommendations and what is being done to assist all the States to adopt those recommendations? And by the way, for our audience, those are recommendations that just follow common public health precepts that have been proven for years to work which were just introduced by CDC 15 months ago.

Dr. FENTON. The Advancing HIV Prevention Initiative was actually launched in 2003 and there are a number of interventions which were included in those, including universal HIV testing of pregnant women, confidential partner notification, and rapid testing. I would like to report on our progress on each of these.

Senator COBURN. OK.

Dr. FENTON. As far as our interventions for pregnant women are concerned, in 2004, CDC recommended implementation of an opt-out testing approach in which women are notified that an HIV test will be routinely included in the standard battery of tests to be done. Since CDC's recommendation for opt-out testing, seven States have specifically authorized opt-out prenatal HIV screening in legislation. In November 2005, the American College of Obstetricians and Gynecologists further published a legislative tool kit of State laws and suggested legislative language that should be used to actually aid the requirement of opt-out testing for pregnant women.

As far as monitoring States and what exactly is happening as far as HIV testing and counseling is concerned, CDC conducted a survey and analysis of all relevant State statutes addressing HIV testing and counseling. An electronic database of these State laws will be posted on the agency website within the next month. This information really has provided a very comprehensive inventory of laws

which really gives a sense of where States are in terms of requiring mandatory HIV testing, pre-testing and post-test counseling, and testing of pregnant women.

As far as our progress on partner notification is concerned, it is a condition for all States receiving Federal funds for HIV and STD prevention that they should have confidential partner notification as a component of partner counseling and referral services. So all CDC grantees are expected to deliver on this intervention.

And then finally, as far as rapid HIV testing is concerned, all CDC grantees are encouraged to use their HIV prevention funds to purchase rapid HIV tests for various clinical and non-clinical sites.

Senator COBURN. Dr. Hopson, Department of HHS has announced the Ninth Annual Ryan White CARE Act Grantee Conference in August, and according to the invitation letter, all participants and presenters are responsible for their own travel, hotel, and registration fees; which should come from CARE Act funds. I have two questions for you. One is, is it really a necessity to have that conference every year when the bill hasn't changed? And number two, couldn't that money be much better spent by redirecting it to an ADAP program?

Ms. HOPSON. Thank you. The Ryan White CARE Act grantee meeting is held every other year, so we don't hold it every year, and we began holding it when the CARE Act programs were combined into the HIV/AIDS Bureau. So this is the fourth biannual meeting. What we have found is that it is the time where we are able to provide technical assistance to our grantees.

As I said in my testimony, this is a time when the CARE Act hasn't changed but the environment in which we are operating has changed. There are lots of changes in Medicare. There are changes in Medicaid. There are changes in other parts of the health care financing world, as well. There are also clinical changes and clinical updates. And so we use this as a time to provide technical assistance to our grantees. Because we have so many grantees, we are not able to get out and visit each one of them and we find that when we bring them together, they are able to learn from each other. This is a time that is well spent and money that we also believe is well spent.

Senator COBURN. How much money is it?

Ms. HOPSON. I will have to provide that for the record.

Senator COBURN. Thank you. The President's reauthorization principles that he put forward would require at least 70 percent of all CARE Act funds to be spent on primary medical care and treatment, and I heartily endorse that. Titles II and III are already spending more than 75 percent of their funds on such purposes, according to GAO. Title I does not, and I understand that most Title IV consumers already have their primary care paid for by either SCHIP or Medicaid. How do you envision the 75 percent primary care floor affecting the roles and services impacted by Title I and Title IV?

Ms. HOPSON. For Title I, we do realize that most of the money does pay for primary care medical services or medications and we believe most of the grantees—when you look at it overall about 54 percent is the amount that they spend on primary care services. So we believe that if the law does pass and it says 75 percent must

be spent on primary care and treatment, then the grantees will have to look and see how they will reallocate funds so that they could meet that requirement.

In terms of Title IV, we realize that there are many of the patients who are eligible for Medicaid and receive their care paid for that way and we are looking to see what would be included in the primary care services. We broadly define that as not only services that are provided for people when they come in for care, but also, we need to provide outreach to get people in care and keep them in care. Those services are vitally important, particularly when you look at the Title IV population, which is largely minority women and their children. There are unique challenges that they face in order to get to care and to remain in care, and so we look at a package of services as part of comprehensive primary care. The Title IV program will try to reprioritize those services, or prioritize such that the Ryan White CARE Act does pay for the primary care services and the necessary support services to get people into care and to keep them in care.

Senator COBURN. OK. I have gone over my 5 minutes. Senator Carper, I am going to come back for another round.

Senator CARPER. Good. Thanks. On our second panel, one of our panelists is Beth Scalco, who is, I think, the Director of the Louisiana HIV/AIDS program. Louisiana is, as we all know, now struggling with the aftermath of Hurricane Katrina, so it is arguably necessary that they have the flexibilities to address some of the new challenges.

I have two questions. One is does the current Ryan White program do enough to give States like the Gulf Coast States and the localities the flexibility to address their specific needs? That is my first question. And second, is there anything more that we ought to be doing in this area?

Dr. Hopson would you start with that and we will just take it from there.

Ms. HOPSON. Hurricane Katrina was certainly something that we have never seen the likes of before in this country and there are many systems that were impacted by that, including the Ryan White CARE Act program. There were many, many evacuees from New Orleans and the other parts of the Gulf region. Included in that evacuation were people who are living with HIV and AIDS. Many of them went to other parts of Louisiana, Alabama, Mississippi that were not impacted by the hurricane. Others went to neighboring States like Texas or Georgia, but the evacuees ended up in many places around the country.

The challenge has been to find all of those patients who were enrolled and receiving care in the affected area and get them into care.

Senator CARPER. That is a pretty big challenge.

Ms. HOPSON. That is a big challenge, and one of the concerns that we have is that we have not found all of those patients. So that is a continuing challenge that we have. We are continually in contact with the States and with all of our grantees around the country to ask if they are still receiving patients who were displaced.

Senator CARPER. Any idea if they have found as many as half of them, three-quarters of them? Just roughly?

Ms. HOPSON. We do have that information. I just don't have it off the top of my head.

Senator CARPER. All right.

Ms. HOPSON. I can give you some specifics. We know that in Texas, there are over 800 evacuees who are receiving CARE Act services. Louisiana received 700 evacuees from New Orleans. We let the grantees know that they were able to have some flexibility so that Title I New Orleans dollars were able to be used by the Title II State. Also, Louisiana Medicaid provided funding to the Texas ADAP to purchase pharmaceuticals for Louisiana Medicaid-eligible clients. In Texas, they really did a yeoman's job of decreasing the complexity of people being eligible for ADAP and were able to very quickly get people enrolled in ADAP, and many of the pharmaceutical companies, as well, immediately stepped up to the plate and were able to provide some free medications for people who were evacuees.

So again, there were lots of things that were done. We were limited, though, by the statute. There were people who were asking me constantly, well, can't you just waive this and waive that? And I said, no, I don't have the power to waive the statute. We still have to follow the law.

Senator CARPER. Excuse me for interrupting, but as we look toward reauthorizing the Act, and people especially like my colleague here, shouldn't we be involved along with folks on the HELP Committee? What ought we be doing to provide more flexibility, if that is appropriate?

Ms. HOPSON. Yes.

Senator CARPER. You can answer that for the record, but it is a timely question.

Ms. HOPSON. It is a great question. We have been having lots of discussions within the Department and I think I would like to provide that answer for the record.

Senator CARPER. Sure. That would be great.

Let me go back, if I could, to Dr. Fenton. I don't think you have been asked enough questions yet, so I will ask you a few more. I understand CDC has suggested that HIV screening be conducted in maybe not all health care settings, but a whole lot of them, unless the patient declines. This seems like a laudable goal, but could you speak a little bit about how this would work on a practical level and how much it might cost to implement that kind of an approach? Finally, how would we pay for it? It is like a three-part question.

Dr. FENTON. It is. To address the first question first, which is which settings and how is this going to be implemented, the real background to this is really to begin to have a systematic strategy to really reduce the undiagnosed fraction of HIV in the general population, and we know that certainly in the American population, approximately 75 percent of individuals attend their health care provider or are seen by a health care provider in the previous year. So this is a huge opportunity for us to really escalate the uptick of HIV testing in the population.

In our revised screening guidelines, the objective is to involve as many health care settings in this process by routinizing HIV testing and removing the barriers to HIV testing in the health care setting. In this respect, we are looking at involving all different kinds of health care settings where individuals aged 13 to 64 would be seen for routine health care.

Senator CARPER. Do you have some idea how much something like this might cost, and finally, who might pay for it? How might we pay for it?

Dr. FENTON. OK. I don't have the figures as to how much this might cost and I would like to provide that for the record?

Senator CARPER. All right. Who might pay for it?

Dr. FENTON. We are looking at various strategies for paying for this. Certainly one area that we are looking at that we would be keen to pursue is exploring the ability for third-party payment for HIV rapid tests, or HIV tests, similar to other screening tests which are done in the population which are paid for by third-party payers. The objective would be to have HIV testing as being paid for in this manner.

We also should remember that additional funds are being provided by the Administration through CDC to support the purchase of rapid tests and we will be working very closely with our partners at State and local government as well as other HHS agencies to ensure that rapid tests are provided in as many settings, both clinical and non-clinical settings, as possible.

Senator CARPER. All right. One last question for you, Dr. Fenton. I understand that CDC has stated that prevention counseling need not be conducted in conjunction with HIV testing. It seems like testing would be a logical point at which to give people information about how to reduce the risk of HIV infection. I am wondering if you can give us some more detail about CDC's thinking in this area.

Dr. FENTON. Absolutely. In thinking about the future of HIV testing in the United States, it is important to unlink the testing which is being recommended in clinical settings from that which is being recommended in non-clinical or community settings. There are no plans afoot to separate prevention counseling in the non-clinical settings. However, in clinical settings, what we are looking at is streamlining the HIV testing process so it becomes shorter, more efficient, and therefore, we begin to remove some of the barriers to HIV testing in the clinical settings.

Individuals who are diagnosed positive as a result of the HIV tests would still have intensive prevention counseling to enable them to access appropriate treatment and care and prevention services. So that part of the process counseling for HIV-positive individuals would not be lost. But it is crucial that if we are moving away from exceptionalization of HIV testing, that we really look at streamlining the HIV testing process, especially in clinical care settings, and removing the barriers, which are time constraints, concerns about stigmatization in providing HIV tests by health care providers, etc.

Senator CARPER. Dr. Crosse, would you care to comment on Dr. Fenton's response?

Ms. CROSSE. Senator, I don't believe that we have the information from the work that we have undertaken to be able to speak specifically to his remarks. If you would like us to review that, I would be happy to do that and provide information subsequently.

Senator CARPER. Thank you, ma'am.

All right, Mr. Chairman. That is it for me. Thanks.

Senator COBURN. I think the answer to your question lies in the chart to your right.[1] A study released last August showed what the cost per infection prevented by the different intervention strategies, and to do HIV counseling with opt-in, one-on-one, the average cost is $110,000.

I find it very interesting that in 1996, the Ryan White CARE Act reauthorization contained a requirement that as a condition of Federal funding, all States require that a good faith effort be made to notify spouses of known HIV-infected patients that such spouse may have been exposed. We just heard testimony from Dr. Crosse that there are two States now that have to have the permission of the person who is infected, and the CDC has certified that all States are requiring with this requirement.

How can CDC certify that if I am a spouse of somebody who is infected who doesn't want to tell me that I am infected that they are, in fact, complying with the Ryan White Act? How can the CDC take that position in those States that require that? You don't have to answer for the record. You can answer in written response, but it is very concerning to me because you hear Dr. Parham say she can't waive the law, and yet my big problem through the years with CDC seems to be that oftentimes what is expedient is waived and what isn't, isn't. So I would love for you to answer that in writing for us because you all have certified that, but we have had testimony today that is something different from that.

Ms. CROSSE. Mr. Chairman, if I could just add, in our review, we only examined the statutes in 12 of the States and so there may be additional States beyond those two——

Senator COBURN. Right.

Ms. CROSSE [continuing]. That have similar requirements.

Senator COBURN. The two out of the 12, you had two where the trump card is if I am HIV infected and I don't want my wife to know, she can't know. The law says you have to not give people money who do that, and yet you certify they are all in compliance. Something isn't right there.

But go back to the chart, which I think is very revealing, and I think what the CDC is trying to address with their specialized nonclinical setting testing and everything else is how do we spend money most effectively to take this large group of undiagnosed people, 300,000, and find out their status so that we don't enlarge the number of people who are unknown in their HIV status who are HIV-positive. But I think this chart is very revealing to us to know where to, in fact, spend our money most efficiently.

Dr. Crosse made some mention about 340B testing in her reports, although they can't be sure because they don't have discounted net prices, rebate net prices. There is some concern that maybe efficiency of the present dollars in ADAP programs aren't as

[1] The chart referred to appears in the Appendix on page 133.

good as they should be because we are not getting a comparison of whether or not they are getting value. Based on what you have heard and based on what your plans are, what are HRSA's plans to do about holding accountable and within the 340B to get more bang for our buck in terms of the dollars spent by ADAP?

Ms. HOPSON. There are a number of things that we do currently. One, HRSA does require the ADAP, as a condition of their grant award, to participate in a cost-saving measure that is equal to or more economical than the 340B program. Now, the problem comes is that HHS cannot disclose the 340B-covered entities, such as ADAPs, what the prices are because of confidentiality agreements between the government and the drug companies. So there is that challenge that we have.

Senator COBURN. But her point was that you are not working with a real number because the numbers they are reporting to you is not rebate-adjusted. Is that correct?

Ms. HOPSON. Yes, that is correct.

Senator COBURN. So basically, whatever you are doing with it, it is not a real number. So is there something you all plan on doing to say, you have to give us rebate-adjusted pricing?

Ms. HOPSON. There is another program within HRSA, the Office of Pharmacy Affairs, and they are not part of my Bureau, so that is why I am turning around to make sure I get the right answer. I know what we are doing in the HIV/AIDS Bureau. But we are working with the Office of Pharmacy Affairs that manages the 340B program to make sure that the information that we get from our ADAPs is the information, the net price, essentially, of the drugs that we purchase through the ADAPs and that we give that information to the Office of Pharmacy Affairs who then can give us a range. They can't give us the exact price, but they can give us, within range, as to what price—are we paying a fair price close to the 340B price or not.

There are a number of things that Dr. Duke, the HRSA Administrator, has put forward to the Department and has put in the 2007 budget request so that we can improve the ability of the Office of Pharmacy Affairs to report to us and work with us so that we can have the accurate prices. On our end, in the HIV/AIDS Bureau, we are working with our grantees, the ADAPs, so that they will report the net price to us so that we then have an accurate number to compare to the 340B prices.

Senator COBURN. So their observation has already been addressed by HRSA.

Ms. HOPSON. Yes.

Senator COBURN. The observation of GAO——

Ms. HOPSON. We are in the process of—this is something we have proposed in the 2007 budget. We don't have that——

Senator COBURN. Dr. Crosse, would you respond to that?

Ms. CROSSE. Our understanding based on HRSA's response to our draft report was that the Office of Pharmacy Affairs was developing a system that would assist the ADAPs in determining for themselves whether or not they were obtaining economical prices in their drug purchasing, but HRSA's response indicated that it would be logistically difficult and require resources that they don't have to carry out the kind of oversight and monitoring that we rec-

ommend they do and that this would not require the sort of manual comparison they indicated in their comments, but could be carried out electronically and could be carried out for a subset of the drugs.

We, for example, in our review looked at just 10 drugs that accounted for 73 percent of the expenditures by the ADAPs so that they could, likewise, examine either on some rotating basis or with some subset that account for a substantial portion of spending, particularly on the anti-retrovirals, what the actual prices finally are or are paid. But our understanding, our reading of their comments back to us was that they did not at this time intend to do that.

Senator COBURN. I just want the panel to know, we are coming back to this, because every dollar wasted is somebody not treated. This is something that the law says and isn't being carried out. You can't waive it and I am going to be the enforcer. So just plan on about 4 months from now finding out what the response is, make sure it is in place, because we are going to have another hearing to ask about it.

If Congress does not reauthorize the CARE Act by October 1, what will happen to the funding of States without names reporting or immature reporting systems? Dr. Hopson.

Ms. HOPSON. As you know, sir, because you were there in 2000, there is a requirement that by 2007, we must use HIV, not just AIDS, in the formula by which we distribute the Title I and Title II dollars. We are discussing that within the Department right now as to the options that we will use for those States that do not have that HIV data that is certified by the CDC, because we use data that is certified by CDC in order to make the funding decisions for Title I and Title II.

Senator COBURN. So tell me again, what is going to actually happen?

Ms. HOPSON. We are having discussions on various options now within the Department——

Senator COBURN. So you haven't made a decision what is going to happen?

Ms. HOPSON. That is correct.

Senator COBURN. OK. That is what I was wanting to get to. Is it important what the Ryan White CARE Act said in terms of the 2001 bill?

Ms. HOPSON. Absolutely.

Senator COBURN. OK. Well, I have several other questions for all of you. I am not going to keep you here for that. I will submit the rest in terms of written format. I would very much appreciate your response in 2 weeks, if you can, and I know those have to be cleared, so I am patient.

But this one issue on ADAP pricing and comparison, whether or not we are getting a good deal, the drug companies don't need to make any more money. They can afford to sell at a reasonable price to ADAPs if they can afford to sell to anybody. It is my concern that this be addressed very quickly because it is money going out of the door that shouldn't be going out of the door. Or, it may not be a problem at all, but the point is, we need to know whether it is. The GAO seems to think it may be, but we don't know. So I want to make sure that is addressed.

I would also invite you to stay to hear our next panel, because I think they have information you all can use, and oftentimes government witnesses don't stay and they don't have the benefit of really getting the feedback that would be beneficial.

Thank you all so much for your testimony and thank you for being here.

Senator COBURN. Our next panel consists of Michael Weinstein, who is President of HIV Healthcare Foundation, the Nation's largest provider of HIV/AIDS medical care. Since 1986, Mr. Weinstein has been a leader in the fight against HIV and AIDS. As President and co-founder of AIDS Healthcare Foundation, he oversees a $140 million organization whose mission is to provide cutting-edge medicine and advocacy regardless of one's ability to pay. They currently serve 30,000 clients in the United States, Africa, Central America, and Asia. The Foundation now operates 14 outpatient AHF health care centers in California and Florida. They also operate seven pharmacies, a clinical research unit, a disease management program through the State of Florida, and the first capitated Medicaid managed care program for people with AIDS.

Beth Scalco is Director of the HIV/AIDS program for the State of Louisiana's Office of Public Health. The HIV/AIDS program under her direction has the primary responsibility for overseeing Louisiana's response to the AIDS epidemic, including all prevention and care activities. Her office administers the Ryan White Title II program, including the ADAP program, the HOWPWA program, the Centers for Disease Control and Prevention surveillance cooperative agreements, and the State general funds for AIDS. She has been working in the field of HIV/AIDS since 1985.

Welcome, both of you. Ms. Scalco, I think I will ask you to go first, since I introduced you second.

TESTIMONY OF M. BETH SCALCO, DIRECTOR,[1] HIV/AIDS PROGRAM, LOUISIANA OFFICE OF PUBLIC HEALTH, AND PAST CHAIR OF THE NATIONAL ALLIANCE OF STATE AND TERRITORIAL AIDS DIRECTORS (NASTAD)

Ms. SCALCO. Good afternoon, Mr. Chairman. My name is Beth Scalco and I am the Director of the HIV/AIDS program for the State of Louisiana. I am also the past Chair of the National Alliance of State and Territorial AIDS Directors (NASTAD). I want to thank you for inviting me to speak with you today.

State AIDS directors appreciate the longstanding support of the U.S. Senate for the Ryan White CARE Act programs, and assuring that all persons with HIV/AIDS, regardless of their geographic location, have equal access to appropriate and high-quality HIV/AIDS services is our highest priority. I would like to share with you some views of my fellow State AIDS directors in addition to some views from the State of Louisiana. I have limited my comments to those that address increasing access to prevention services provided by State health departments, including testing and access to life-saving drugs provided by the AIDS Drug Assistance Program.

[1] The prepared statement of Ms. Scalco appears in the Appendix on page 64.

As you said, Louisiana HIV/AIDS program administers the HIV/AIDS prevention and care programs funded by both State and Federal funds. HIV infections have penetrated both our metropolitan areas as well as our rural areas in our State. In 2004, the State of Louisiana had the 11th highest number of AIDS cases reported and the fifth highest AIDS incident rates in the Nation. There were a total of 25,846 cumulative cases of AIDS reported in Louisiana and there are currently 14,793 individuals living with HIV/AIDS in Louisiana as of March 2006.

In 2005, we identified 967 new HIV/AIDS cases in Louisiana. We normally identify around 1,100 cases in Louisiana, and I am sad to say, I do not think that HIV infection decreased. I believe that is a result of the impact on our ability to test in the months following Hurricane Katrina.

In the Federal fiscal year 2006, Louisiana received over $22 million in Ryan White CARE Act funding. We received $6 million for Title II base, $15 million for ADAP, and $950,000 for our emerging communities, which is Baton Rouge, Louisiana. Our Title I EMA, which is New Orleans, received $7.4 million. We received close to $5 million in HIV prevention cooperative agreement funds and $1.6 million for our surveillance cooperative agreement.

The State of Louisiana contributes approximately $2.5 million specifically for HIV prevention activities in Louisiana. In addition, they contribute over $9 million for care and treatment of people who are HIV infected through the State's public hospital system. This is in spite of Louisiana's ongoing budget deficits both prior to the hurricane, and I, unfortunately, have to say, I do not believe that they will not be able to continue this contribution as a result of the hurricane.

State public health agencies serve an essential and a unique role in the delivery of HIV/AIDS prevention, care, and treatment programs. The agencies are entrusted through the U.S. law as the central authorities of the Nation's Public Health System and as such bear the primary public sector responsibility for health. State Public Health responsibilities include disease surveillance, epidemiology, prevention programs, immunizations, emergency preparation, provision of primary health care services for the uninsured and the indigent, and overall planning and coordination, administration, and physical management of Public Health Services.

The President's 2007 budget includes $93 million, of which $86 million is new funding, to increase testing in medical settings, make voluntary testing a routine part of medical care, and to create new testing guidelines, models, and best practices. The President's initiative will prioritize funding for regions with the highest number of new cases as well as focusing on incarcerated persons and injection drug users.

State AIDS directors support the President's request for $86 million in new funding for domestic HIV prevention and believe that this funding should be allocated via the prevention and surveillance cooperative agreements with State and local health departments. State and local health departments already fund HIV testing in a variety of venues in communities and they are in the best position to maximize the potential of the President's testing initiative.

However, testing alone will not prevent new infections. Funds must be increased to make up for 3 years of cuts, which have hampered the ability of State health departments to implement CDC's Advancing HIV Prevention Initiative.

In addition, resources for surveillance are sorely needed, as the Federal Government shifts prioritization from AIDS to HIV case reporting and funding for core surveillance activities has eroded significantly in recent years.

State AIDS directors support the delivery of HIV prevention services in primary care settings as a standard of care. Studies indicate that HIV-positive individuals who are aware of their status take steps to protect their partners from infection, with 70 percent reporting reductions in risky behaviors. Health departments use partner counseling and referral services as one tool to identify HIV-positive individuals and ensure their linkages to medical support and prevention services.

Research has found PCRS to be a very cost-effective strategy for identifying HIV-infected persons who are unaware of their serostatus. State AIDS directors support the continuation of funding for PCRS through CDC cooperative agreements with States and the directly-funded cities.

The State AIDS programs have been one of the largest implementors of HIV rapid testing programs. We have long supported the development and approval of rapid testing and worked collaboratively with Congress and the Administration to ensure rapid tests were considered for a CLIA waiver. In several jurisdictions and in certain settings, barriers to rapid testing exist. It is a complex testing technology. In addition, it is more costly to implement than traditional testing.

The CARE Act is a safety net under other public programs, such as Medicaid and Medicare. The Ryan White programs must adapt to fill gaps particular to the individual State. ADAPs work closely with the State Medicaid programs and Medicare Part D to ensure that ADAPs remain the payer of last resort. Annually, ADAPs serve approximately 136,000 clients, or about 30 percent of the people living with HIV/AIDS estimated to be receiving care in the United States.

In fiscal year 2005, States were dependent on State contributions to their ADAP programs and pharmaceutical discounts and rebates to sustain their ADAP programs, as the increase in Federal dollars for ADAPs was extremely limited. ADAPs receive the lowest prices in the country for anti-retroviral therapies. In 2003, NASTAD established the ADAP Prices Task Force to negotiate with the pharmaceutical industry on behalf of all ADAPs, and as a result of this highly successful public-private partnership, the task force achieved supplemental discounts and rebates beyond those mandated by the 340B program and price freezes that have resulted in over $300 million in savings over the past 3 years.

Ten years after the advent of highly active anti-retroviral therapy, the lives of people living with HIV/AIDS have been greatly extended. Therefore, individuals are remaining on our ADAP programs for lifetimes. ADAPs across the country continue to encounter significant challenges in fiscal stability while adequately serving the growing number of people with HIV and AIDS.

For 2007, State AIDS directors seek an increase of $197 million for ADAPs to maintain those that are currently enrolled and to meet the growing demand of new clients and to strengthen ADAPs' abilities across the Nation to provide the PHS standard of care and treatment.

Senator COBURN. Could you summarize, please? You have gone past your 5 minutes.

Ms. SCALCO. Sure. I would like to summarize by saying that, first of all, State waiting lists for the ADAP programs are only one indicator of need, that many ADAPS have other restrictions in place, and to solely distribute money on the basis of a waiting list is not an equitable way to do it.

I would also like to take one moment to address the issue of Hurricane Katrina and the State of Louisiana, and particularly since you asked the question about the flexibility provided by our Federal partners. What we found is that the flexibility was lacking and that, in fact, what occurred is that while we were trying to piece programs back together and provide services to clients, what basically was occurring is that we were also having to meet administrative requirements that could not be waived, which was not nearly as important as assuring that people had access to treatment and care. We also needed to have waivers of certain conditions of award and that has not been possible. The transfer of funding between Title I and Title II, which should have been an easy thing to do, actually could not be done without amending 20 contracts through the State of Louisiana's contract system.

And so in that, I would say I would appreciate in the Ryan White CARE Act reauthorization if there is an emergency provision that would address this problem. Thank you.

Senator COBURN. Thank you. Mr. Weinstein.

TESTIMONY OF MICHAEL WEINSTEIN,[1] PRESIDENT, AIDS HEALTHCARE FOUNDATION

Mr. WEINSTEIN. Senator Coburn, Senate staff and the audience, as President of the largest AIDS organization in the United States, I am deeply concerned about the lack of access to HIV medical care for half a million Americans. As we approach the 25th anniversary of the identification of the first cases of AIDS, I am troubled by our lack of progress in treating HIV and controlling the epidemic in this country.

Our No. 1 priority in all matters relating to AIDS should be protecting the public health. With half the people who are positive not in treatment, including many who do not even know their status, we cannot control the spread of this disease nor adequately help the people who have it.

AIDS Healthcare Foundation's primary mission is the medical treatment of HIV in this country and across the globe, serving 32,000 patients. In several of the communities AHF serves, HIV patients are dangerously underserved. As an example, Alameda County, which includes the City of Oakland, is only spending 10 percent of its Ryan White CARE Act monies on primary medical care. The Magic Johnson Clinic, which we operate in Oakland, is

[1] The prepared statement of Mr. Weinstein appears in the Appendix on page 76.

largely unfunded and specialty referrals are almost impossible to obtain. Despite the fact that Alameda County has declared a state of emergency around HIV, much more money is being spent on social services than medicine. At our Magic Johnson Clinic in Jacksonville, Florida, the situation is similar.

Ten years after the discovery of the miraculous drug cocktails that have made HIV a treatable illness, we are treating HIV as if it is a death sentence that it was in the 1980s. We reauthorized the Ryan White CARE Act 5 years ago without making the necessary adjustments to reflect the progress we have made in treating patients, and there are some who would have us do this again this year.

We know what it takes to control this disease. We must identify most of the carriers and get them into treatment, and we must effectively educate the uninfected population. Despite billions of dollars a year in expenditures to combat AIDS, we are failing on all counts. One need merely look at the numerous countries, both rich and poor, that are succeeding where we have failed to understand why. We don't do enough tests. We don't provide enough money to treat. We are spending too much money on drugs. We are not putting sufficient responsibility on the infected person to protect their partners.

Until we have treatment readily available to everyone who needs it, we will continue to have more and more AIDS cases. Until testing is taken out of the rarified atmosphere of an anonymous test site and integrated into mainstream medical care in hospitals, clinics, and doctors' offices, we will not identify many of the people who are positive. Until we tell the drug companies that the U.S. Government will not write a blank check for purchasing HIV drugs, we will continue to have waiting lists for the AIDS Drug Assistance Program. Until we are honest with people about the consequences of becoming infected by HIV, which is not a day at the beach, as the drug company ads portray it as, we will fail to fight AIDS effectively in America.

The solutions are quite simple. If you want to improve access to care, require that the lion's share of Federal dollars be spent on treating the disease. We are doing this in Los Angeles. The result is an extensive network of outpatient clinics, both public and private, across the vast geography of Southern California. Alameda County would have the same diversity of treatment options if most of their money were not being spent on food, housing, transportation, case management, and everything else.

If you want to find more positives, you need to test more people in a fast, convenient, and cost-effective manner. Routine testing in health care settings without onerous counseling requirements is the only way to go.

If you want to make drugs more accessible to more patients, you cannot pay higher and higher prices for each new generation of drugs, including those that are developed at government expense, thus eating up most of the new money that Congress has appropriated.

If we identify more people who are positive and get them into treatment, the number of new infections will go down. If it goes

down below the number of deaths, then the number of people living with HIV will be less each year rather than more.

We need to resolve to put the money where it is most needed to stop AIDS. Rural areas and cities with emerging epidemics must get a bigger piece of the pie. Distributing funds based on where the epidemic was 10 years ago will not help us fight it where it is found today. The people most hurt by this are people of color, who represent the overwhelming majority of new cases of AIDS.

Public health and politics are a dangerous mix. Too many decisions about how to address AIDS have been made on the basis of how one constituency or another must be appeased. This has led to a piecemeal, half-hearted approach that has led us to where we are now. There is no more fundamental function of government than the protection of the public health.

I strongly urge the Congress to reauthorize the Ryan White CARE Act in a fashion that will protect generations to come from this devastating illness, and I would ask you to take another look at other areas of AIDS spending, such as vaccines and research, where there is enormous waste of public resources. If these changes are adopted now, I am confident that in the United States—this has happened in a country like Uganda, that I returned from last week and I have visited eight times—we will have less AIDS down the road rather than more. Thank you.

Senator COBURN. Thank you.

Ms. Scalco, I may have heard you wrong, and I skimmed your testimony. Was it your testimony that rapid testing is more expensive than standard counseling testing and results? Is that your testimony?

Ms. SCALCO. Rapid testing is more expensive to implement than doing Orasure testing and it has to do with the cost of the kit and the cost of the controls and the cost of the other supplies related to rapid testing.

Senator COBURN. As compared to an Orasure test?

Ms. SCALCO. Yes.

Senator COBURN. OK, which can be, in fact, done very easily?

Ms. SCALCO. Yes. However, with the Orasure, you have to wait approximately 2 weeks for results. We are very much in favor of rapid testing. It has given us the ability to get results to people much quicker and it assists with people who don't return for their results.

Senator COBURN. We know many thousands of people don't come back every year——

Ms. SCALCO. Right.

Senator COBURN [continuing]. Who test positive.

Ms. SCALCO. So, yes, we would like to implement more rapid testing.

Senator COBURN. But you are looking at the cost of the test only. You are not looking at the cost of the test to identify.

Ms. SCALCO. Yes. We are looking at the costs of the actual test as being more expensive.

Senator COBURN. But the cost to identify that somebody is HIV-positive, a rapid test is far less expensive than the other——

Ms. SCALCO. That is correct.

Senator COBURN. OK. I wanted to clarify that.

Mr. Weinstein, we have known each other for quite some time. You just espoused in your testimony a true public health approach to HIV. My thought on this as I listened to the testimony from CDC, 10 years ago, I tried to get the CDC to do testing for newborn infants. It was blocked. The American College of Obstetricians and Gynecologists was against it. Gary Ackerman and myself, bipartisan, one Democrat liberal, one Republican conservative, were totally blocked by the political forces.

So I take what you say very seriously, but my response is, how do we get other people embracing public health strategies instead of political strategies when it comes to HIV? How do you help me do that?

Mr. WEINSTEIN. Just in the last 2 weeks, we passed historic legislation in California to bring about names reporting for the first time. It took us a long time, but we built a coalition and in the end, it was unanimous.

Senator COBURN. Why did that happen?

Mr. WEINSTEIN. It happened, first of all, I believe immodestly, because groups like us were willing to stand up and say it was necessary. I think also, when we enacted the code system, it was horrible. And then lastly, the threat of losing Ryan White CARE Act funds. But whatever it took, it happened.

We have a bill in the legislature now to simplify testing. We are talking about routine testing. Let me tell you how it actually works in the field today. It takes longer to do a routine test because of the regulations of CDC and the State of California than it took previously to do the other test. It takes 40 minutes to do a test. Now, how many people can we test if we do that?

Also, in this country, if you want to get a free test in most places, you are required to answer a long list of intimate sexually explicit questions to a total stranger. If you go to a doctor, you don't have to do it. But if you want to do it in a public setting, the price you have to pay is to answer questions about the most intimate aspects of your life. I don't think that is right.

Also, it was said earlier by the CDC that in a doctor's office, we are going to uncouple counseling from testing. But in the public setting, we are not going to do it. Well, that is wrong, I would say, because 80 percent of the people we test, and we have the largest testing program in California, are repeat testers. No. 1, they have the information, and No. 2, the last word they hear in that counseling session is "negative" or "positive." If a person is positive, they need intensive counseling not just on that occasion, but following it, as well, to make sure they get into care. We have to be practical.

If we are actually going to test more people, we have to do it differently, and also, I would say, I am sure this will not be a surprise to you to hear, but what is enacted in Congress is not implemented in many cases. The reality is across this country that women are not informed that their husbands or boyfriends are infected with HIV. Most women who we treat, and we have a large women's program, have no known risk factor for HIV. I don't know how long we have been talking about it, but it is not happening. And I think, again, going back to your question about how we enacted names re-

porting, unless there is a concrete penalty for not doing it, it will never be done, and I think that is a terrible thing.

Senator COBURN. Why is that? I mean, if this is a public health strategy we use in other areas, why is it that CDC won't move to a common sense public health strategy that works? I am not saying that they haven't made some movement. They have, and I compliment them on that. But I am the author of informed science about the effectiveness of condoms that passed this Congress in the year 2000 which still hasn't been implemented by the CDC saying people ought to know the level of protection they get from a condom. With HIV, it is wonderful. It is great. With many other diseases, it is not. But that is never a part of the counseling.

The point being is how do we get to the point where we embrace public health strategies where we can save lives, where we can prevent, in fact? How do we move past the politics? In other words, you are out there on the activist side of this. Ms. Scalco is on the implementation side of it. How do we move to where we get policies that are efficient and effective, that save lives, move the ball forward, spend the money where it is going to give us the best return in terms of life and quality of life? How do we move to that? How do we build that?

Mr. WEINSTEIN. Well, I would argue that since we are fighting AIDS as a global effort, and I know there is always a tension between States' rights and Federal directives, but there are laws in California and elsewhere that prevent many of these things from being done, as you heard earlier. Therefore, I think that because you can't fight AIDS town by town and city by city and State by State, I think there ought to be a Federal standard that is enforced, at least in some of these areas.

And I think that when it comes to partner notification, it shouldn't be voluntary, because if there is a group of sexually active people and they know that they have a risk, they are making that as an informed choice. But a woman who is not aware that her husband or a woman who is not aware that her boyfriend is using drugs or is bisexual is not able to make that choice. I think that is a societal obligation and I don't see any problem, really. Given the fact that the Federal Government is the primary funder, I don't see a problem with the Federal Government requiring in exchange for that funding that this be universal.

Senator COBURN. If somebody is diagnosed with syphilis in one of your clinics, is there mandatory reporting of that?

Mr. WEINSTEIN. Yes.

Senator COBURN. Is there partner notification?

Mr. WEINSTEIN. Ineffectively, but it is supposed to. It is not done effectively, but yes, there is.

Senator COBURN. It is supposed to be, though?

Mr. WEINSTEIN. It is supposed to be. It is done to some extent, but not as fully as it should be.

Senator COBURN. But it is supposed to be.

Mr. WEINSTEIN. Yes.

Senator COBURN. And there are statutes and regulations to back that up.

Mr. WEINSTEIN. Yes.

Senator COBURN. Would you consider HIV more deadly than syphilis?

Mr. WEINSTEIN. Oh, there is no question about that.

Senator COBURN. So why would we not have the same policy for a disease that is more deadly?

Mr. WEINSTEIN. How I look at it is if you look back over 25 years and you look at the ineffective Federal response, you look at the stigma and discrimination that was even more intense then but still exists now, myself and many activists felt that the first order of business was privacy, protection, and rights. I think that what the problem is, that we had a revolution in treatment of HIV and when the disease goes from being a death sentence to being a manageable illness, things change. When you look back historically about how we used to handle breast cancer, when Betty Ford and Nancy Reagan came out publicly about it, all of a sudden, the paradigm shifted and now there is public discussion and advocacy. It is totally transformed.

So, I mean, it takes a while to catch up to these technological changes, but I think guidance needs to be given, again, by the Federal Government, which is the most expert. The Centers for Disease Control is the most expert. They know what works. I think they should give that guidance.

Senator COBURN. Thank you. Ms. Scalco, you all have an EMA in New Orleans. Were funds transferred from that EMA to help you with some of the programs that you had during the midst of this hurricane and the things that followed thereafter and the disruption in care and treatment for patients?

Ms. SCALCO. Yes. We ultimately were able to transfer funds through contractual arrangements so that the funding could follow clients who had evacuated to other parts of the State.

Senator COBURN. Is Louisiana put at a disadvantage because under the former formula we are using former AIDS diagnosis instead of HIV? Would Louisiana benefit in terms of funding formulas if the basis was where the disease is now and not where it used to be?

Ms. SCALCO. We believe that we may benefit. We believe that we could have benefitted if that had been instituted earlier in the epidemic. I think right now, we need to see where other States stand in terms of their HIV infections. But we definitely——

Senator COBURN. We have run those numbers. You will benefit, I promise you.

Ms. SCALCO. Yes, we may benefit, and in actuality, we are serving people who are HIV infected and so we would like them counted in the formula distribution.

Chairman COBURN. I have several other questions, but I am going to shorten our hearing because we have something on the floor at 4 o'clock. I want to thank you for your testimony. I am committed for us to getting the Ryan White CARE Act reauthorization. It doesn't have to be mine. It does need to address the public health aspects of this. It does need to address diagnosis, prevention, but also care and medical treatment of those who have it. We know this is a disease that can be controlled. We also know that with the early testing, we can markedly decrease the number of potential infections in the future coming from that one vector, and so

it is important that we all figure out where we can find the most common ground and get this to happen before the end of this year.

I appreciate your work, both of you, in terms of trying to get this done, and the others that have been here today. My commitment is to work to get that done.

Thank you very much. The hearing is adjourned.

[Whereupon, at 4:07 p.m., the Subcommittee was adjourned.]

APPENDIX

Testimony
Before the Committee on Homeland Security and Governmental Affairs
Subcommittee on Federal Financial Management, Government Information and International Security
United States Senate

CDC's Progress in Reducing Barriers to HIV Testing and Improving Opportunities for Early Diagnosis

Statement of
Kevin Fenton, M.D., Ph.D.
Director
National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:30 pm
Wednesday, April 26, 2006

Introduction

Good afternoon Mr. Chairman and Members of the Subcommittee. My name is Kevin Fenton and I am the Director of the National Center for HIV, STD, and TB Prevention at the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to discuss CDC's progress in reducing barriers to HIV testing and improving opportunities for early diagnosis and linkage to care.

Twenty-five years ago, the first cases of AIDS were reported in the United States. Although the struggle to prevent new HIV infections is not over, we have made substantial progress and achieved major successes. For instance, the dramatic decrease in mother-to-child (perinatal) HIV transmission is one of the great success stories of HIV prevention. CDC estimates that between 140 and 230 infants infected with HIV through mother-to-child transmission were born in the United States in 2002 – a substantial reduction from the estimated peak of 1,750 HIV-infected infants born each year during the early to mid-1990's. These declines are due to multiple interventions, including routine voluntary HIV testing of pregnant women, the use of rapid HIV tests at delivery for women of unknown HIV status, and the use of antiretroviral therapy by HIV-infected women during pregnancy and by infants after birth.

We have also seen declines in the number of HIV and AIDS cases attributed to injection drug use. For example, from 2000 to 2004 the number of AIDS cases attributed to injection drug use has declined by about 15%.

Despite these major successes, HIV infection and AIDS remain a leading cause of illness and death in the United States. The numbers are sobering--through December 2004, an estimated total of 944,306 persons have been diagnosed with AIDS and 529,113 (56%) of these persons have died. CDC estimates that currently 1 to 1.2 million people in the United States are infected with HIV, and of these, 252,000-312,000 (roughly a quarter) are undiagnosed and at high risk for transmitting HIV. This undiagnosed group is of great concern to us because they are not able to take advantage of medical treatment and because we believe that infections transmitted by people who are unaware that they are HIV positive account for more than half of new HIV infections each year. Knowledge of one's HIV infection can help prevent the spread of HIV to others. When people know their status, they are more likely to protect their partners from infection. For these reasons, efforts to increase HIV testing and diagnosis are an important part of CDC's HIV prevention strategy.

Early Diagnosis Efforts

The advances made in HIV treatment have dramatically improved HIV/AIDS survival rates, especially since 1996, when highly active antiretroviral therapy first became available. However, insufficient progress has been made in effecting earlier diagnosis. In 2004, an estimated 39% of persons diagnosed with AIDS first tested positive for HIV within 1 year of their AIDS diagnosis—a modest improvement—compared with 51% of those diagnosed from 1990 to 1992.

Those who develop AIDS soon after their HIV diagnosis likely have been infected with HIV for years without knowing it and thus have not received the benefits of medical treatment or preventive services. Persons tested late in their infection are more likely to be African-American or Hispanic and to have been exposed through heterosexual contact.

Currently, CDC has a number of efforts underway to encourage early diagnosis of HIV infection. In 2003, CDC launched the Advancing HIV Prevention initiative (AHP), which reinforces CDC's evidence-based approach that routine HIV testing implemented in a variety of settings will reduce barriers to HIV testing, will improve opportunities for early diagnosis and linkage to prevention and care, and will help reduce the number of new infections. CDC also encourages its funded partners—state and local health departments and directly funded community-based organizations—to take HIV testing out into the community by using rapid tests in nontraditional settings and in health care settings that provide episodic care, such as emergency rooms. In addition, CDC is currently updating guidelines for testing in health care settings, making HIV testing more routine. Finally, the President's 2007 budget contains an increase in funding aimed at increasing the number of people who know their HIV serostatus through promoting rapid testing in areas with a high incidence of HIV infection.

Advancing HIV Prevention Initiative

The AHP initiative represents a multi-agency collaboration within the Department of Health and Human Services and consists of four key strategies for HIV prevention: make HIV testing a routine part of medical care; implement new models for diagnosing HIV infections outside medical settings; prevent new infections by working with persons diagnosed with HIV and their partners; and further decrease perinatal HIV transmission.

In 2003, nine health departments and 16 community-based organizations were awarded $23 million for 2-year demonstration projects to develop models for demonstrate effectiveness in implementing the four AHP strategies. One project used social network strategies to reach persons at high risk for HIV infection in communities of color and demonstrated the feasibility of using these social networks to encourage HIV counseling, testing, and referral services. These strategies involve enlisting HIV-infected and high-risk HIV-negative individuals in affected communities to encourage members of their social, sexual, and drug-using networks who may be at risk for HIV to be tested. Of the 3,139 network associates tested though this project, 173 of them tested HIV positive (a positivity rate of 5.5%), which is over 3 times the average prevalence reported by publicly funded counseling, testing, and referral sites. This strategy proved to be successful in reaching persons with undiagnosed HIV infection and to be an efficient and effective route to access HIV-infected persons. As a result in 2005 CDC issued a "Dear Colleague" letter in 2005 that formally encouraged funded grantees to implement the social networks strategy. CDC is currently developing

a social networks toolkit, an implementation manual, and training curriculum that includes technical assistance strategies for CDC grantees targeting women of color and men who have sex with men.

A second AHP demonstration project, the Antiretroviral Treatment Access Study II (ARTAS II), explores the effect of linked case management on getting HIV-infected persons into care. In the linked case management approach, a person who has recently received an HIV diagnosis is assigned a case manager to ensure that he or she accesses HIV primary care.

ARTAS II is a follow-up to the ARTAS I study, which showed that when persons with a recent diagnosis of HIV infection meet up to 5 times in a 3-month period with a case manager, they have a greater chance of being linked to care. In comparison, persons with a recent diagnosis of HIV infection who receive only a passive referral are less likely to be linked to care. ARTAS II will compare linkage rates to HIV care providers before and after instituting linked case management. The study findings will strengthen our understanding of how well linked case management works in HIV program settings in the United States. CDC is also working with the Health Resources and Services Administration (HRSA) to develop additional strategies to link newly diagnosed persons to care and treatment services.

Expanding Rapid HIV Testing

In 2003, access to testing was expanded when the Food and Drug Administration gave HIV rapid tests a Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver, which allowed HIV rapid testing to be performed outside of traditional laboratory settings. Rapid HIV testing is quickly becoming the accepted standard for HIV screening tests, especially in settings such as emergency departments and STD clinics that deliver mainly episodic care and typically do not establish ongoing relationships with patients. To help promote the use of rapid tests among our partners, CDC purchased $6.4 million worth of rapid HIV test kits between FY 2003 and FY 2005. More than 500,000 rapid HIV tests were distributed to 197 health departments and community-based organizations in 36 states. Heath departments and community-based organizations have used their CDC HIV prevention dollars to purchase tests as well. The President's 2007 budget contains a funding increase to make rapid testing available to several million additional Americans at greatest risk.

Routinizing HIV screening in health-care settings

To reduce barriers to HIV testing and increase the opportunity for early diagnosis, CDC is proposing to revise our guidelines for HIV testing of adults, adolescents, and pregnant women in health care settings. The revised guidelines will focus on increasing routine HIV screening of patients in health care settings; fostering the earlier detection of HIV infection; identifying and counseling persons with unrecognized HIV infection and linking them to clinical

and prevention services; and further reducing perinatal transmission of HIV in the United States.

There are several reasons for the proposed revisions. First, many HIV-infected persons access health care but are not tested for HIV until they become symptomatic (very late in their infection); second, persons testing late in the course of the disease are unable to benefit fully from the effective treatment available; and third, data show that awareness of HIV infection leads to substantial reductions in high-risk sexual behavior.

Many persons with HIV infection visit health care settings in the years before their diagnosis, yet they are infrequently tested for HIV. The changing demographics of the HIV/AIDS epidemic in the United States—with rising proportions of infected persons among youth, women, racial and ethnic populations; persons who reside outside metropolitan areas; and heterosexual men and women—has made it harder for risk behavior-based testing to detect many HIV-infected persons.

Historically, prevention strategies or programs that incorporate universal HIV screening have been highly effective. Screening blood donors for HIV has virtually eliminated transfusion-associated HIV infection in the United States. The incidence of perinatal HIV infection in the United States has also declined

dramatically since the 1990s when prevention strategies began to include specific recommendations for routine HIV testing of pregnant women.

Although the number of new perinatal HIV infections per year is low, transmission continues to occur mostly among women who lack prenatal care or who are not offered voluntary HIV counseling and testing during pregnancy. Even though CDC recommends screening of all pregnant women, studies from a limited number of jurisdictions have shown that such screening is not yet universal. With universal screening of pregnant women in combination with prophylactic administration of antenatal antiretroviral drugs, perinatal transmission rates could be reduced to less than 2%.

Routinizing HIV screening eliminates many significant barriers to HIV testing such as time constraints associated with targeted risk assessments, pre-test HIV counseling, and stigma associated with requesting or consenting to an HIV test. The new guidelines will recommend routine (or opt-out) HIV screening in health care settings. Under this approach, the patient is notified that HIV screening is routine for all patients and has the opportunity to ask questions and decline testing. HIV testing should not take place without a patient's knowledge.

Studies in acute care settings demonstrate that routine HIV screening programs are more effective in identifying HIV-positive persons than are targeted screening programs. For example, in settings such as hospitals and emergency

departments, the percentage of patients with positive tests (2% to 7%) often exceeds that observed nationally in publicly funded HIV counseling and testing sites (1.5%) and sexually transmitted disease (STD) clinics (2.0%) serving high-risk persons. In studies that have examined this issue, patients in acute care settings were rarely seeking testing when screening was offered; therefore, many people were identified earlier than might otherwise have been the case. Routine testing also reduces the stigma associated with having to disclose behavioral risks. More patients accept recommended HIV testing when it is offered routinely to everyone, without a risk assessment.

Data from targeted testing programs in acute-care settings show that nearly two-thirds of patients accept screening, but because risk assessment and prevention counseling (features of targeted testing programs) are resource intensive, only a small number of eligible patients can be tested. Targeted testing on the basis of behavioral risks also fails to identify many HIV-infected persons, as many persons do not perceive their HIV risks or do not disclose them.

Another important feature of the recommendations is that screening may be eligible for third-party reimbursement, analogous to other recommended screening (such as mammography or cholesterol screening). Detecting HIV infection earlier through HIV screening (and optimizing opportunities for effective treatment and prevention) has been shown to be cost-effective, even in settings of low HIV prevalence.

The proposed HIV testing recommendations are intended for providers in all health care settings, including hospital emergency departments, urgent care clinics, inpatient services, STD clinics, correctional health care settings, tuberculosis and other public health clinics, community clinics, and primary care settings. The guidelines only address HIV testing in health care settings; they do not modify existing guidelines on HIV counseling, testing and referral for high-risk persons who seek or receive HIV testing in nonclinical settings (for example, in community based organizations and outreach settings such as testing vans.)

Provision of Counseling in Revised Guidelines

In the proposed guidelines, the provision of counseling at the time of disclosure of results will not change from current practices for persons who test positive for HIV. Furthermore, the guidelines will continue to recommend linking those who test positive to care and prevention services. However, prevention counseling (i.e., pre-test counseling with the development of a risk reduction plan, and post-test counseling for HIV-negative persons) will not be required in conjunction with HIV screening programs in health care settings. Several studies have shown that both patients and providers often perceive prevention counseling as a significant barrier to testing in medical settings. Because of time constraints and other considerations, when conventional counseling and testing are recommended for health care settings, most patients receive neither.

Additionally, data from the National Health Interview Survey indicate that, by the mid-1990s, the U.S. population exhibited high levels of knowledge about HIV, HIV testing, and risk factors for HIV transmission. Emerging data suggest that singling out HIV testing is likely to perpetuate the stigma surrounding HIV testing.

Potential barriers to early diagnosis

Legislative and statutory barriers to early diagnosis exist at the federal, state, and local levels. Some states and local jurisdictions may have statutory or other regulatory impediments prohibiting opt-out screening, or may impose other specific requirements for HIV counseling, written informed consent, confirmatory testing, or method for communicating HIV test results. Current federal law also impacts the way counseling and testing services are delivered in federally funded facilities.

Since the initiation of the AHP Initiative, CDC has recognized the potential for existing state laws to impact the performance of multiple AHP-related activities focused on increasing knowledge of serostatus. Barriers to early diagnosis do currently exist. For example, 40 states currently legislate who can order an HIV test. Some states only allow physicians and nurses to order a test, while other states allow persons from a broad range of disciplines (from midwives to dentists to nursing home administrators) to order an HIV test. About half of the 50 states require informed written consent before an HIV test can be conducted. These legislative provisions often stem from efforts to protect the rights and privacy of

those infected and were often adopted before statutory and regulatory protections were put into place to protect this information.

Many states also promote the use of HIV tests through administrative codes or state public health agency policy. While the majority of states encourage the use of rapid HIV tests, only two states specifically promote the use of rapid HIV tests through legislation. CDC is working with states to resolve barriers that might conflict with CDC's recommendations (both current and proposed).

At the federal level, the Ryan White CARE Act requires counseling before testing of HIV disease. This provision, which was added by the Ryan White Care Act Amendments in 2000, is not consistent with CDC's proposed recommendations for HIV testing in health care settings. While this requirement was consistent with CDC recommendations at the time, qualitative data now show that prevention counseling may not always be appropriate or feasible (such as during episodic or acute care visits) and can serve as a barrier to testing.

President's HIV Testing Initiative

To further support the goal of diagnosing HIV infections earlier and increasing access to care, the President's 2007 budget includes an increase of $93 million for CDC HIV prevention programs. Several components are included in this increase. A testing in Healthcare and Non-Clinical Settings Initiative ($52 million) will support outreach and testing for 2 million individuals in health-care and non-

clinical settings and referral, where appropriate. The initiative is expected to identify approximately 30,000 undiagnosed cases. CDC intends to target resources to areas with the greatest need, including jurisdictions with high HIV/AIDS prevalence among African Americans and areas with emerging epidemics. CDC will work closely with the HRSA to ensure that those identified with HIV infection are linked to appropriate care and treatment.

A Jail Testing Initiative ($20 million) will focus on testing of inmates. With $15 million, CDC will directly facilitate the testing of more than 600,000 incarcerated persons. An additional $5 million will support work with the Department of Justice to develop a model HIV/AIDS policy for corrections agencies that will address testing, prevention education, staff and peer training, and discharge planning programs and procedures as part of a comprehensive community re-entry package. Those programs will link HIV-infected individuals to appropriate community prevention counseling and treatment services when released.

An Injecting Drug User Testing Initiative ($21 million) will test approximately 500,000 injection drug users and is expected to help identify approximately 7,500 undiagnosed cases. CDC will work collaboratively with the Substance Abuse and Mental Health Services Administration on this effort.

Closing

Over the past 25 years, our nation has made progress in preventing morbidity and mortality related to HIV. Beginning in the late 1980s, the number of new HIV infections among men who have sex with men declined dramatically. In the 1990s, improved treatments led to improved longevity and decreased deaths, as well as decreases in perinatal infections. In this, the third decade of the epidemic, we are making progress in increasing early diagnosis, which is key to further reducing incidence, illness, and death from HIV. CDC remains committed to helping people live longer, healthier lives by preventing new HIV infections and protecting the health of those already infected. This includes ensuring fewer barriers to HIV testing, improving opportunities for early diagnosis, and linking HIV-infected persons to prevention services and medical care.

Thank you again for this opportunity. I will be pleased to answer any questions.



Testimony
Before the Committee on Homeland Security and Governmental Affairs
Subcommittee on Federal Financial Management, Government Information and International Security
United States Senate

HRSA Efforts to Ensure Early Diagnosis and Improve Access for Persons Living With HIV/AIDS

Statement of
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U.S. Department of Health and Human Services
HRSA
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Mr. Chairman, Members of the Subcommittee, thank you for the opportunity to meet with you today on behalf of the Health Resources and Services Administration (HRSA). Last year, I testified before the Subcommittee regarding the Domestic HIV/AIDS Care Programs and I am happy to be here today to discuss ways to ensure early diagnosis and improve access to treatment for Americans living with HIV/AIDS. I appreciate your continuing support of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Programs.

Introduction

The Ryan White CARE Act is the centerpiece of our domestic response to care and treatment of low income, uninsured and underinsured individuals living with HIV/AIDS. Currently funded at $2.06 billion, it provides primary health care, life saving medications, and support services to individuals who lack health insurance and financial resources to provide adequate health care for themselves. The Ryan White CARE Act was enacted in 1990; it was amended and reauthorized in 1996 and again in 2000. The authorization for the CARE Act programs expired on September 30, 2005. President Bush in his State of the Union Address stressed the importance of this program and asked Congress to "reform and reauthorize the Ryan White Act and provide new funding to states so we can end the waiting lists for AIDS medicines in America."

Since its last reauthorization, we have been able to provide antiretroviral treatment, primary care, and support services to over half a million people

annually in the United States, Puerto Rico, Guam, the U.S. Virgin Islands, and eligible U.S. territories. In 2004, an estimated 65 percent of these individuals were racial minorities, 33 percent were women, and 87 percent were either uninsured or received public health benefits. The Ryan White CARE Act programs have provided important benefits to these populations. Overall, AIDS mortality is down and lives have been extended with HIV/AIDS medications purchased through the AIDS Drug Assistance Program (ADAP). Pregnant HIV positive women have been provided with care that has allowed them to give birth to children free from HIV infection, and thousands have received support services that have allowed them to access and remain in health care.

Although we are making progress in providing services to people living with HIV/AIDS, the epidemic continues and will be in need of our attention for some time to come. The President and the Secretary understand the dynamics and severity of the epidemic and they are committed to ensuring the Department's HIV/AIDS programs are as effective as possible in preventing infection and treating those who become infected. We have recognized that, as essential as the CARE Act has been to serve Americans living with HIV/AIDS, it is in need of revitalization to safeguard its critical mission. Despite record levels of funding, we continue to face waiting lists for life-saving drugs through the ADAP program, and there are marked disparities in access to quality medical treatment across the country. As minority populations are increasingly and disproportionately impacted by HIV/AIDS, changes to existing systems of care designed for an

earlier epidemic are increasingly urgent. We are challenged as never before to make sure that Federal funds are directed where they are most needed and used for the most vital purposes.

Advancements

When AIDS was first recognized in the United States in the 1980s, medications to effectively treat the underlying immune deficiency did not exist. Today, although a cure has not been found, the introduction of Highly Active Antiretroviral Therapy (HAART) has had a tremendous impact on the morbidity and mortality associated with AIDS. Life-saving treatments have led to an increasing number of persons with HIV in the United States living longer lives. From 1999 to 2003, the number of persons in the U.S. living with AIDS rose from 311,205 to 405,926 – an increase of 30 percent.

Currently, 27 medications have been approved by the Food and Drug Administration (FDA) for the treatment of HIV/AIDS, including NRTIs (nucleoside reverse transcriptase inhibitors), PIs (protease inhibitors) and fusion inhibitors. A total of 84 HIV/AIDS related drugs, including vaccines, antivirals, antiinfectives, cancer treatments, immunomodulators, antifungal, gene therapies, and nine other medicines are currently in clinical trials or before the FDA awaiting approval. These life-saving treatments and related primary care services, however, come with a stiff price tag, ranging from $18,000 - $30,000 per year per patient.

Today, care and treatment advances have significantly reduced AIDS mortality, yet there has not been a corresponding reduction in the number of new infections, still estimated at 40,000 each year. In addition, of the estimated 1,039,000 – 1,185,000 persons in the U.S. with HIV/AIDS, 252,000 – 312,000 are undiagnosed and unaware of their HIV infection. HRSA's collaboration with the Centers for Disease Control and Prevention (CDC) on the Advancing HIV/AIDS Prevention Initiative together with the President's 2007 Domestic HIV/AIDS Initiative will go a long way in diagnosing and bringing these individuals into care. We must assure that the CARE Act programs are in a state of readiness to receive a growing number of newly diagnosed persons and link them into effective primary care and treatment.

Current State of the Disease

The HIV/AIDS epidemic is growing most rapidly among minority populations and is a leading killer of African-American males ages 25 to 54. African-Americans account for 50 percent of all HIV/AIDS cases diagnosed in 2004. The disease is also taking an increasing toll on women in the U.S., accounting for a growing percentage of new AIDS cases, rising to 27 percent of the cases diagnosed in 2004. Women of color, particularly African-American women, have been hard hit and represent the majority of new AIDS cases among women, an estimated 82 percent. The primary mode of HIV transmission is sexual contact, followed by injection drug use for women.

Current State of the CARE Act

The CARE Act, with appropriations of $2.06 billion, funds primary health care and support services for individuals living with HIV disease who lack health insurance and financial resources to pay for their care. HIV/AIDS health care is the largest component of Federal funding for people living with HIV/AIDS in the U.S. Each year, the CARE Act programs, primarily through grants to States, metropolitan areas, providers and educators, reach an estimated 571,000 underserved persons – more than half of those living with HIV/AIDS in the U.S. Medicare and Medicaid, the largest payers of HIV/AIDS health care, served an estimated 355,000 persons in FY2005 at a projected cost of $8.6 billion dollars in Federal funds. Since AIDS was first recognized, the pattern and treatment of HIV disease has shifted. We now strive to manage HIV/AIDS as a chronic disease.

The CARE Act is often the first line of defense for persons living with HIV/AIDS who are uninsured or underinsured. Early diagnosis and improved access to HIV care and treatment is key to what the CARE Act stands for. Funding under Titles I and II of critical early intervention services that include counseling, testing, and referral services for persons at high risk for HIV infection was expanded in the 2000 amendments. In 2004 alone, over 121 organizations received CARE Act funds to provide early intervention services under Titles I and II (or Parts A and B); a total of 359 organizations were funded under Title III (or Part C), a majority of which were community based health centers. An additional 91 programs were funded under Title IV (or Part D), a program designed with a focus on providing

access and early entry to care for HIV infected women, infants, children and youth, as well as supportive services to affected family members.

CARE Act funded programs are successful at counseling and testing. In 2004, over 800,000 HIV tests were administered in CARE Act sites. Over 85 percent of persons tested in CARE Act sites returned for their results. This was primarily because the CARE Act sites also were primary care settings which linked persons testing positive into immediate care and treatment.

Prevention and early intervention go hand in hand. Our medical care providers reported serving 5,375 HIV-positive pregnant women in 2004. Fifty-one percent were in care during the first trimester of their pregnancy. The percentage of pregnant women receiving prenatal care rose to 76 percent by the second trimester. Eighty-one percent received antiretroviral (AVR) treatment to prevent transmission of HIV to their child. The significant decline in perinatal transmission of HIV is a true success story and testament to the impact that targeted efforts such as those made by CARE Act programs can have, especially within our Title IV program. Early intervention services also include efforts to reach and provide early access to people living with HIV/AIDS who know their status but are not receiving HIV-related health services. In 2004, 506 CARE Act programs were funded to provide these outreach services, facilitating enrollment or re-entry into care and treatment efforts for over 35,000 HIV-positive clients and additional 59,000 HIV-affected persons. However, even with this successful

outreach effort, less than half of all HIV infected persons who know their status are in care.

Going Forward

We take great pride in the advances in HIV/AIDS care and treatment that have been made by the CARE Act programs over the past 16 years. However, we are humbled by the significant challenges that remain for people living with HIV/AIDS who have nowhere else to go for care in an age of increasing HIV/AIDS prevalence, increasing health care costs, and a growing burden of HIV among the uninsured and underinsured. With authorization of the Ryan White CARE Act pending, now is the time to make the necessary changes to ensure that individuals living with HIV/AIDS are better served by the Act.

The Administration has emphasized five key principles for reauthorization of the Ryan White CARE Act: (1) serve the neediest first; (2) focus on life-saving and life-extending services; (3) increase prevention efforts; (4) increase accountability; and (5) increase flexibility. The President has made fighting the spread of HIV/AIDS a top priority of his Administration, and he will continue to work with Congress to encourage prevention, and provide appropriate care and treatment to those suffering from the disease.

The President's fiscal year 2007 budget request for the CARE Act HIV/AIDS activities is $2.16 billion, an increase of $95 million for several elements of a new

Domestic HIV/AIDS initiative (further elements of that initiative, focusing on testing in the areas of greatest need, are requested outside the CARE Act). The request will support a comprehensive approach to address the health needs of persons living with HIV/AIDS, consistent with reauthorization principles. The budget also includes a new authority to increase program flexibility by allowing the Secretary to transfer up to five percent of funding provided for each Part of the Ryan White CARE Act to any other Part if the need warrants it. Of the new $95 million requested, $70 million will address the on-going problem of State waiting lists and provide care and life-saving medications to those newly diagnosed as a result of increased testing efforts. The remaining $25 million will be used to expand outreach efforts by providing new HIV community action grants to intermediaries including faith and community-based organizations, and to provide technical assistance and sub-awards to grassroots organizations.

Today, people with HIV/AIDS are living longer and healthier lives in part because of the CARE Act. In order to make the legislation more responsive in the future, the Administration urges Congress to take into account the above stated principles in the reauthorization of the Ryan White CARE Act.

Thank you for the opportunity to discuss the Ryan White CARE Act today and for your dedication and interest in such an important piece of legislation.

United States Government Accountability Office

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Testimony

Before the Subcommittee on Federal Financial Management, Government Information, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate

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RYAN WHITE CARE ACT

AIDS Drug Assistance Programs, Perinatal HIV Transmission, and Partner Notification

Statement of Marcia Crosse
Director, Health Care



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April 26, 2006

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Highlights

Highlights of GAO-06-681T, a testimony before the Subcommittee on Federal Financial Management, Government Information, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate

RYAN WHITE CARE ACT

AIDS Drug Assistance Programs, Perinatal HIV Transmission, and Partner Notification

Why GAO Did This Study

Despite progress in HIV/AIDS drug treatments and the reduction of AIDS mortality in the United States, challenges remain concerning the availability of these drugs for individuals with HIV/AIDS and the prevention of new cases. The CARE Act authorizes grants to the states and certain territories specifically for AIDS Drug Assistance Programs (ADAP) to purchase and provide HIV/AIDS drugs to eligible individuals. In its report issued today, *Ryan White CARE Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs* (GAO-06-646), GAO examines the program design of ADAPs in the 50 states, the District of Columbia, and Puerto Rico, their funding sources, and drug purchasing. GAO also reports on state approaches to reducing perinatal HIV transmissions and identifying and notifying partners of HIV-infected individuals.

What GAO Recommends

In its report, GAO recommends that HRSA require ADAPs to report the final prices they paid for drugs, net of any rebates, and that HRSA routinely determine whether these prices are at or below the 340B prices. In commenting on these recommendations, HRSA stated that these steps would be labor intensive and it lacks capacity to carry out such oversight.

www.gao.gov/cgi-bin/getrpt?GAO-06-681T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov.

What GAO Found

Variation in ADAPs' program design and funding amounts from CARE Act grants and other funding sources contribute to differences in coverage—who is eligible and what drugs are covered by an ADAP—among the 52 ADAPs GAO reviewed. In order to make maximum use of the funding they receive, ADAPs are expected to secure the best price available for the drugs on their formularies. ADAPs may, but are not required to, purchase their drugs through the 340B federal drug pricing program, under which drug manufacturers provide discounts on certain drugs to covered entities. The Health Resources and Services Administration (HRSA) has identified the 340B prices as a measure of ADAPs' economical use of grant funds, but the Department of Health and Human Services does not disclose 340B prices to the ADAPs. GAO found that some ADAPs reported prices that were higher than the 340B prices for selected HIV/AIDS drugs. However, these reported prices may not have reflected any rebates ADAPs eventually received. While HRSA is responsible for monitoring whether ADAPs obtain the best prices available for drugs, it does not routinely compare the drug prices ADAPs report to 340B prices.

All 50 states, the District of Columbia, and Puerto Rico have policies or have enacted laws regarding HIV testing of pregnant women to help reduce perinatal HIV transmission. The majority of states have adopted a policy of voluntary prenatal HIV testing of pregnant women that is consistent with guidelines issued by the Centers for Disease Control and Prevention (CDC). GAO contacted 8 states to discuss the approach they use to test pregnant women for HIV, and these states use one of two approaches. Consistent with additional CDC recommendations on testing, three states routinely include HIV tests in standard prenatal testing, but a woman can refuse to be tested for HIV. In the other 5 states, a woman must consent to an HIV test, usually in writing, before the test can be performed. Six of the 8 states GAO contacted report that the number of HIV-positive newborns has declined. However, only 3 states GAO contacted collect the data needed to determine statewide perinatal HIV transmission rates.

GAO contacted 12 states regarding their approaches to identifying partners of HIV-infected individuals and notifying them of their possible exposure to the virus. These states used various approaches in conducting HIV partner notification activities as part of their partner counseling and referral services. These activities include eliciting partner information from HIV-infected individuals, but the participation of these individuals varies and not all partners can be reached to be notified. Of the 12 states contacted, 10 have statutory or regulatory provisions that require or permit certain health care entities or workers to notify partners, including spouses, without the consent of the known HIV-infected individual. In the remaining two states, public health officials or the health department may notify partners only with the consent of the HIV-infected individual.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the AIDS Drug Assistance Programs (ADAP) that receive funds under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act)[1] and to provide a summary of our report that we are releasing today entitled *Ryan White CARE Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs*, which was prepared at your and others' request.[2] The report discusses the program design of 52 ADAPs in the 50 states, the District of Columbia, and Puerto Rico, their funding sources, and drug purchasing. I will also discuss our examination of state prenatal HIV testing and perinatal HIV transmission rates, and state approaches to identifying and notifying partners of HIV-infected individuals.

The CARE Act authorizes ADAP base grants to the states and certain territories specifically for ADAPs to purchase and provide HIV/AIDS drugs to eligible individuals. ADAPs serve as the HIV/AIDS drug assistance program of last resort for individuals who, for example, cannot afford to pay for drugs, do not have insurance coverage for drugs, or do not qualify for other federal programs such as Medicaid. As more people with HIV/AIDS live longer due to improved drug treatments, particularly highly active antiretroviral therapy, the demand for ADAP services will increase, and expenditures by ADAPs for HIV/AIDS drugs will also likely increase. It is, therefore, important that ADAPs achieve the maximum benefit they can with the funds provided to them for drug purchases. ADAPs may purchase their drugs through the 340B federal drug pricing program, under which drug manufacturers provide discounts on certain drugs to covered entities.[3] Generally, ADAPs can purchase drugs through either the 340B direct purchasing option, where ADAPs receive the 340B price discount upfront, or through the 340B rebate option, where ADAPs later request a

[1]Pub. L. No. 101-381, 104 Stat. 576 (codified as amended at 42 U.S.C. §§ 300ff—300ff-111 (2000)). Unless otherwise indicated, references to the CARE Act are to current law.

[2]GAO-06-646 (Washington, D.C.: Apr. 26, 2006). We previously reported to you on Ryan White CARE Act funding; see GAO, *HIV/AIDS: Changes Needed to Improve the Distribution of Ryan White CARE Act and Housing Funds*, GAO-06-332 (Washington, D.C.: Feb. 28, 2006).

[3]Under Section 340B of the Public Health Service Act, a 340B price, sometimes referred to as a 340B ceiling price, is established for each covered drug that entities purchase. 42 U.S.C. § 256b (2000). Covered entities include, for example, community health centers and hemophilia treatment centers.

340B rebate from the drug manufacturers. The Health Resources and Services Administration (HRSA) administers CARE Act grants and is responsible for monitoring the prices ADAPs pay for drugs. HRSA has identified prices under the 340B federal drug pricing program as a measure of an ADAP's economical use of its grant funds.

In carrying out this work for our report, we interviewed HRSA and other officials, analyzed and compared data ADAPs reported on program design, funding, and drug prices paid, compared 340B drug prices to prices available under other federal drug pricing programs, and interviewed officials from selected states about prenatal HIV testing and partner notification. We performed our work in accordance with generally accepted government auditing standards. The report's appendix III provides a more detailed explanation of our scope and methodology.

In summary, we report that variation in ADAPs' program design and funding amounts contributed to differences in who and what was covered by each program, that some ADAPs reported prices that were higher than the 340B prices for selected HIV/AIDS drugs, that HRSA is not routinely comparing the drug prices ADAPs pay to 340B prices, and that 340B prices were higher for some selected drugs than the prices available under other federal drug pricing programs. However, these latter prices are not available to ADAPs, except for prices under one program to the District of Columbia ADAP. We also report that the majority of states have adopted a policy of voluntary prenatal HIV testing of pregnant women that is consistent with guidelines issued by the Centers for Disease Control and Prevention (CDC) for reducing perinatal transmission of HIV, and most of the 8 states we contacted reported that the number of HIV-positive newborns has declined. Further, among efforts to reduce the transmission of HIV, the 12 states we contacted used various approaches to conduct HIV partner notification activities as part of their partner counseling and referral programs, but cooperation of infected individuals varies.

ADAPs' Program Design and Additional Funding

Variation in ADAPs' program design and funding amounts from the CARE Act grants and other funding sources contributes to differences in coverage—who and what is covered by an ADAP. Because of the variation in program criteria, an individual eligible for ADAP services in one state may not be eligible for or receive the same ADAP services in another. ADAP income ceilings for individuals, program enrollment caps, and drug formularies vary considerably among ADAPs. For example, each ADAP determines a maximum income level, or income ceiling, as a criterion for an individual's eligibility for enrollment. ADAPs reported income ceilings

for the 2004 grant year that ranged from 125 percent of the federal poverty level in North Carolina to 556 percent in Massachusetts. Sixteen ADAPs reported that they had limits on the assets that individuals enrolled in the program are allowed to have. Twelve ADAPs reported having caps on program enrollment or on amounts expended per individual for HIV/AIDS drugs. The total number of drugs ADAPs included on their formularies ranged from 20 in Colorado to 1,000 in Massachusetts, New Hampshire, and New Jersey.

The additional funding that some ADAPs reported receiving from sources other than the ADAP base grant, such as transfers from other CARE Act grants, and states' or other governmental entities' funds, also varied among ADAPs for fiscal year 2004. Funding from these various sources significantly increased funds available to cover individuals for some ADAPs. For example, in addition to receiving funds from the ADAP base grant of about $89.6 million, the California ADAP received about $123.5 million from other sources.

ADAPs' Reported HIV/AIDS Drug Prices

ADAPs are expected to use every means at their disposal to secure the best price available for the drugs on their formularies. ADAPs are eligible, if they so choose, to participate in the federal 340B drug pricing program. Generally, ADAPs can purchase drugs through either the 340B direct purchasing option or through the 340B rebate option. Drug manufacturers that participate in the 340B drug pricing program agree to sell drugs to 340B entities, including ADAPs that participate in the program, at prices no higher than 340B prices.

HRSA has identified the 340B prices as a measure of ADAPs' economical use of grant funds, whether ADAPs use the 340B program, including the 340B prime vendor—which negotiates prices directly with drug manufacturers for ADAPs using the 340B direct purchase option—or negotiate drug prices on their own with drug manufacturers. However, the Department of Health and Human Services does not disclose to the ADAPs or the 340B prime vendor what the 340B prices are that should not be exceeded—a situation which disadvantages both the prime vendor's and the ADAPs' negotiating positions.

In our analysis using the top 10 HIV/AIDS drugs by ADAP expenditures, we found that in 2003 all of the 25 ADAPs that used the 340B direct purchase option reported prices to HRSA that were higher than the 340B price for at least 1 of the top 10 drugs. For example, 7 of the 25 ADAPs reported purchasing the drug Viramune at prices higher than the 340B price. Of the

27 ADAPs that used the 340B rebate option to purchase drugs in 2003, all except 3 ADAPs reported paying drug prices that were higher than the 340B prices for many of the top 10 drugs. However, the prices that ADAPs using the rebate option report to HRSA for each drug they purchase may not reflect the rebates that they eventually receive and therefore may not be the final prices these ADAPs pay for the drugs.

HRSA's Monitoring of ADAPs' Reported Drug Prices

Although HRSA is responsible for monitoring whether ADAPs obtain the best prices available for drugs, it does not routinely compare the drug prices ADAPs report to 340B prices. Further, the ADAP drug price information that HRSA currently uses to make its comparisons is not complete. The reported prices do not reflect the rebates eventually received by ADAPs using the 340B rebate option to purchase drugs. Without the final ADAP rebate amount on a drug purchase, HRSA cannot determine whether the final drug prices paid were at or below the 340B price.

In the report we are releasing today, we are recommending that HRSA, to ensure that ADAPs are obtaining the best prices for the drugs they provide, require ADAPs to report the final prices they paid for drug purchases, net of rebates, and that HRSA routinely determine whether these prices are at or below the 340B prices. In commenting on these recommendations, HRSA stated that it would like to verify final drug prices but this would be labor intensive because reports ADAPs currently provide do not contain the needed information. HRSA further stated that it lacks the resources to conduct a comprehensive price comparison, but is making efforts to develop systems to allow ADAPs to check drug prices. As we stated in our report, however, while monitoring the prices paid for all the drugs on each ADAP's formulary might be challenging, HRSA could compare ADAP reported prices to 340B prices for selected drugs and could modify its schedule of ADAP reports to allow for rebate reconciliation.

340B Prices and Other Federal Drug Pricing Programs

We found that the 340B program prices were higher for some of the top 10 drugs than the 340B prime vendor prices and the prices federal agencies paid for the same drugs under the federal supply schedule (FSS) and federal ceiling price (FCP) drug pricing programs.[4] Using the top 10 HIV/AIDS drugs by ADAP expenditures, we compared 2003 drug prices under the 340B prime vendor, FSS, FCP, and Medicaid programs to the 340B prices. We found that the FCP and 340B prime vendor prices were lower than the 340B prices for 6 of the 7 drugs that had prices available under all five programs. The 6 HIV/AIDS drugs were Combivir, Epivir, Sustiva, Trizivir, Zerit, and Ziagen. The Medicaid prices,[5] available to state Medicaid programs, were consistently higher than the 340B program prices and were the highest of all the drug pricing programs for 3 of the 7 drugs for which we had prices from all programs. The 3 drugs were Norvir, Sustiva, and Trizivir.

Prenatal HIV Testing and Perinatal HIV Transmission Rates

When pregnant women are infected with HIV, they can transmit the virus to their infants during pregnancy, during labor and delivery, or after delivery through breast-feeding. Antiretroviral therapy can reduce the risk of HIV transmission from mother to child. According to CDC, the prevention of perinatal HIV transmission depends on routine testing of pregnant women for HIV and the use of antiretroviral drug treatment and obstetrical interventions. All 50 states, the District of Columbia, and Puerto Rico have policies or have enacted laws regarding HIV testing of pregnant women to help reduce perinatal HIV transmission. The majority of states have adopted a policy of voluntary testing of pregnant women that is consistent with CDC's guidelines. We contacted eight states to discuss the approach they use to test pregnant women for HIV. The eight states we contacted—California, Connecticut, Illinois, Louisiana, Michigan, New Jersey, New York, and North Carolina—use two approaches. Consistent with additional CDC recommendations on testing, three states routinely include HIV tests in a standard battery of prenatal testing, but a woman can refuse to be tested for HIV. In the other five states, a woman is counseled during prenatal care and must consent to an

[4]The FSS has prices available to all federal government purchasers for the drugs listed on the schedule. The FCP is the maximum price that drug manufacturers can charge four agencies—the Department of Defense, the Department of Veterans Affairs, the Public Health Service, and the Coast Guard—for the brand-name drugs listed on the FSS, even if the FSS prices are higher. The District of Columbia ADAP has access to the FCP.

[5]The Medicaid price is the average amount state Medicaid programs paid net of the basic rebate provided under the Medicaid Drug Rebate Program.

HIV test, usually in writing, before a test can be performed. Of the eight states that we contacted, three—Connecticut, New Jersey, and New York—collect the data needed to determine statewide perinatal HIV transmission rates. Six of the eight states we contacted reported that the number of HIV-positive newborns declined in their state from 1997 to 2002.

Identifying and Notifying Partners of HIV-Infected Individuals of Possible HIV Exposure

Research suggests that most new HIV infections originate from HIV-infected persons not yet aware of their infection.[6] This emphasizes the need to identify HIV-infected persons and link them with appropriate services as soon as possible. The Ryan White CARE Act Amendments of 1996 provided for states to take action to require a good faith effort be made to notify spouses who may have been exposed to HIV. Partner counseling and referral services (PCRS) assist HIV-infected persons with notifying their partners, including spouses, of their exposure to HIV.[7] We contacted 12 states to determine what approaches they use to identify and notify partners of HIV-infected individuals.[8] These states use various approaches in conducting HIV partner notification activities as part of their PCRS programs. These activities include eliciting partner information from known HIV-infected individuals—referred to as index cases[9]—and notifying the partners of their possible exposure to the virus. The states use a variety of entities and individuals trained to conduct these activities. Of the 12 states we contacted, 10 have statutory or regulatory provisions that require or permit certain health care entities or workers to notify partners, including spouses,[10] without the consent of the index case. In the

[6]G. Marks, N. Crepaz, J. W. Senterfitt, and R. S. Janssen, "United States: Meta-Analysis of High-Risk Sexual Behavior in Persons Aware and Unaware They Are Infected with HIV in the United States," *Journal of Acquired Immune Deficiency Syndromes*, vol. 39, no. 4 (2005).

[7]CDC's PCRS guidance for HIV defines PCRS as a prevention activity with the goals of (1) providing services to HIV-infected persons and their sex and needle-sharing partners so they can avoid infection or prevent transmission to others, and (2) helping partners gain earlier access to individualized counseling, HIV testing, medical evaluation, treatment, and other prevention services.

[8]The 12 states we contacted were California, Connecticut, Florida, Kentucky, Massachusetts, Minnesota, Missouri, New York, North Carolina, Pennsylvania, Texas, and Washington.

[9]Index case is a generic term for a person who has tested positive for HIV and is asked to name spouses and partners at the start of the notification process.

[10]The North Carolina provision applies only to notification of spouses; state officials told us that they generally notify partners with the consent of the index case.

remaining two states, public health officials or the health department may notify partners only with the consent of the HIV-infected individual. The participation of HIV index cases in PCRS program activities varies. Not all HIV-infected individuals are willing to share the names of their partners and not all partners can be reached to be notified.

Some states reported integrating their HIV partner notification activities with established programs that are focused on syphilis and other sexually transmitted diseases, or STDs.

Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions that you or other Members of the Subcommittee may have.

Contact and Acknowledgments

For future contacts regarding this testimony, please contact Marcia Crosse at (202) 512-7119 or at crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. James McClyde, Assistant Director; Robert Copeland; Helen Desaulniers; Cathy Hamann; Martha Kelly; Daniel Ries; Opal Winebrenner; Craig Winslow; and Suzanne Worth made key contributions to this statement.



Testimony for Submission by

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To the Senate Subcommittee on Federal Financial Management, Government Information, and International Security of the Homeland Security and Government Affairs Committee

For the oversight hearing "Ensuring Early Diagnosis and Access to Treatment for HIV/AIDS: Can Federal Resources Be More Effectively Targeted?"

Wednesday, April 26, 2006, 2:30 p.m.

The Louisiana HIV/AIDS Program respectfully submits testimony for the record regarding the importance of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act and the CDC HIV/AIDS prevention program in assisting Louisiana to provide prevention, care, and treatment services to low-income persons living with HIV/AIDS and those at risk for contracting HIV/AIDS. I also serve on the Executive Committee of the National Alliance of State and Territorial AIDS Directors (NASTAD) and former chair of the organization. I am submitting this testimony on behalf of NASTAD as well. State AIDS directors appreciate the longstanding support of the United States Senate for the Ryan White CARE Act and domestic prevention programs that are of the utmost importance to Americans living with HIV/AIDS.

As the past chair of NASTAD, I would like to share with you some of the views of my fellow state AIDS directors, in addition to the state of Louisiana. I have limited my comments to those that address increasing access to prevention services provided by state health departments, including testing, and life-saving drugs provided by the AIDS Drug Assistance Program (ADAP) and.

The Louisiana HIV/AIDS Program administers Louisiana's HIV/AIDS prevention and care programs, which are funded by federal and funds. HIV infections have penetrated both metropolitan and rural communities in our state. Over 50 percent of Louisiana's AIDS cases are outside of our one Title I eligible metropolitan area (EMA), New Orleans. In 2004, the state of Louisiana had the eleventh highest number of AIDS cases reported and the fifth highest AIDS incidence rate in the nation. There are a total of 25,846 cumulative cases and 14,793 individuals living with HIV/AIDS in Louisiana as of March 31, 2006. In 2005, 967 new HIV/AIDS cases were detected in Louisiana. We have had approximately 11,198 Louisianans die as a result of having HIV/AIDS (as of the end of 2005). Of those living with HIV/AIDS, the vast majority are members of minority groups: 66 percent are Black, three percent are Latino and one percent are

Asian American, Pacific Islander or Native American. Seventy-four percent of newly detected HIV cases were among African Americans. Women make up 28 percent of living HIV/AIDS cases compared to 77 percent for men.

In federal fiscal year 2006, Louisiana received $18.9 million in Ryan White CARE Act funding for Titles I and II – including $6 million for the Title II base, $15 million for ADAP, and $950,512 for our one emerging community – Baton Rouge. Louisiana's one Title I EMA, New Orleans, was funded at $7.4 million. Louisiana received $4.9 million for our HIV prevention cooperative agreement and $1.6 million for our surveillance cooperative agreement with CDC. Governor Blanco and the Louisiana legislature have demonstrated a commitment to HIV/AIDS care and treatment by providing $2.5 million in state funds for prevention and over $9 million for treatment of people living with HIV, through the state's public hospital system, in spite of Louisiana's budget deficit.

Role of Public Health in HIV/AIDS

State public health agencies serve an essential and unique role in the delivery of HIV/AIDS prevention, care and treatment programs. The agencies are entrusted through U.S. law as the "central authorities of the nation's public health system" and as such, bear the primary public sector responsibility for health. State public health responsibilities include: disease surveillance; epidemiology and prevention; provisions of primary health care services for the uninsured and indigent; and overall planning, coordination, administration, and fiscal management of public health services. As such, unlike other CARE Act grantees, states have on overall responsibility in coordinating HIV/AIDS services provided by the CARE Act and other federal programs in each state.

Importance of State Public Health Prevention Programs

HIV prevention and surveillance programs are funded by the Centers for Disease Control and Prevention (CDC) under general authority provided by federal public health law. Since 1988, CDC has provided HIV prevention resources to 65 state, local, and territorial health departments to implement comprehensive HIV prevention programs in their jurisdictions. In FY2005, states, local, and territorial health departments received $301 million for these efforts. States conduct the following efforts as part of their comprehensive HIV prevention programs:

- *Counseling, Testing, Partner Counseling, and Referral Services* aimed at ensuring that individuals and their partners learn their HIV serostatus, receive counseling on behavior change to avoid infection or prevent transmission, and obtain referrals for prevention and care services.
- *Health Education/Risk Reduction* provides support for, and technical assistance on, targeted education and outreach activities for individual, group, and community-level interventions and street and community outreach.
- *Community Planning* to ensure the participation of infected and affected communities in the development of effective HIV education and prevention interventions.
- *Capacity Building* to strengthen the delivery of effective prevention programs.
- *Prevention Research and Program Evaluation* to monitor progress, outcome and impact of the programs they support, as well as to assess needs and develop culturally appropriate services.

The President's FY2007 budget includes $93 million, of which $86 million is new funding, to increase testing in medical settings, make voluntary testing a routine part of medical care, and create new testing guidelines, models and best practices. According to the President, this initiative would facilitate the testing of more than three million additional Americans. The President's initiative would prioritize funding for regions with the highest numbers of new cases as well as focusing on incarcerated persons and injection drug users.

State AIDS directors support the President's request for $86 million in new funding for domestic HIV prevention and believe this funding should be allocated via the prevention and surveillance cooperative agreements with state and local health departments. State and local health departments fund HIV testing in a variety of settings in their communities and are in the best position to maximize the potential of the President's testing initiative. However, testing alone will not prevent new infections. Funds must be increased to make up for three years of cuts which have hampered the ability of health departments to implement CDC's Advancing HIV Prevention Initiative.

Importance of Surveillance

HIV/AIDS epidemiology, surveillance and seroprevalence activities provide data that are critical to targeting the delivery of HIV prevention, care and treatment services. State health agencies are uniquely positioned to conduct these activities because of the expertise, statutory authority, and confidentiality protections of existing public health disease surveillance and reporting systems. States conduct a variety of surveillance activities to track the HIV/AIDS epidemic. In FY2005, states, local, and territorial health departments received $68 million for these efforts.

The five main types of surveillance are the following:

- *Core surveillance* is the primary source of population-based data on persons living with HIV and AIDS in the U.S.
- *Incidence Surveillance* provides reliable and scientifically valid estimates of the number of newly-acquired HIV infections though collection and testing of blood specimens from all newly reported HIV infections; calculation of population-based estimates for HIV incidence; and monitoring and tracking HIV strains for resistance to antiretroviral drugs.
- *Behavioral Surveillance* is a multi-year, CDC sponsored surveillance effort whose goal is to measure an extensive set of HIV risk behaviors and related risk factors among selected high-risk populations in 26 cities with the highest number of people living with HIV/AIDS (as of the end of 2000).
- *Morbidity Monitoring Project* (MMP) is a surveillance system under development that will be nationally representative of HIV-infected persons receiving medical care in the U.S. The system utilizes HIV care providers to collect necessary data.
- *Enhanced Perinatal Surveillance* monitors progress made in reducing perinatal HIV transmission.

Resources for surveillance are sorely needed as the federal government shifts prioritization from AIDS to HIV case reporting and funding for core surveillance has eroded significantly in recent years.

Integration of Prevention into Care Setting

Federal agencies, health departments, and communities understand the growing importance of close linkages between HIV prevention and care services to ensure that individuals learn their HIV status and receive referrals to appropriate services. State AIDS directors support the delivery of HIV prevention services in primary care settings as the standard of care. Studies indicate that HIV-positive individuals take steps to protect their partners from infection, with 70 percent reporting reductions in risky behaviors.

Health departments use partner counseling and referral services (PCRS) as one tool to identify HIV-positive individuals and ensure their linkage to medical, support, and prevention services. Research has found PCRS to be a cost effective strategy for identifying HIV infected persons unaware of their serostatus. The CARE Act also allows Titles I and II to conduct early intervention services (EIS) such as counseling and testing, outreach and referral services, provided those programs are not duplicated with existing CDC programs. Previously, early intervention activities were only allowed among Title III and IV grantees. The 2000 CARE Act amendments also added grants to states for carrying out programs providing PCRS. While the CARE Act called for $30 million to be appropriated in FY2001 for the new PCRS grants, no money has ever been provided to states through this grant mechanism.

Currently, all states and territories conduct PCRS as a requirement of their prevention cooperative agreement through the CDC. PCRS includes three basic elements: 1) Seeking the names of partners who may be at risk for infection (partner elicitation), 2) Locating partners and notifying them of their risk (partner notification), and 3) Providing HIV testing and risk reduction counseling to partners (partner counseling). PCRS is not limited to the time of initial diagnosis but is offered continuously to provide on-going support for positive persons related to serostatus disclosure and to ensure that both positive persons and their partners have access to prevention services. Partner notification, a key public health strategy to fight communicable disease, lies within the authority of health departments as part of their mission to protect public health.

State AIDS directors support the continuation of funding for PCRS through the CDC cooperative agreements with the states and six directly funded cities.

Importance of Testing

The CDC is finalizing their "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings." State AIDS directors participated in the development of these guidelines, including attendance at two CDC consultations. We are supportive of these guidelines. CDC should work with health departments on the publication of an implementation guide for health departments. Many health departments are playing a central role in implementing and supporting routine screening in key health care settings (particularly emergency rooms, STD clinics, acute care clinics, etc.) within their jurisdictions. Experiences and recommendations from these programs would serve to facilitate expanding the number of health departments implementing and supporting testing in these settings.

Over the past several years, health departments have moved resources from settings with low HIV prevalence and low testing yields to target high prevalence settings where the majority of positive persons are found. These moves have met with resistance from local health departments

and community agencies, often in rural areas. Recent studies supporting the cost effectiveness of screening in very low prevalence settings has created confusion on the role of public health and has caused resistance to health department efforts to refocus funding. These recommendations will potentially create further confusion. Given limited funding, public health resources must be targeted toward settings where they will most likely identify the greatest number of positives. Third party payers must be encouraged to reimburse for testing for routinization of testing to be realized.

While many jurisdictions may have statutes or regulations with specific requirements for consent, provision of pre-test information and delivery of results, this does not mean these statutes and regulations pose a barrier to routine testing. Many jurisdictions have already implemented routine testing in these settings and proven their ability to work within their current statutes and regulations.

State AIDS programs are one of the largest implementers of HIV rapid testing programs. We have long supported the development and approval of rapid testing and worked collaboratively with Congress and the Administration to ensure rapid tests were considered for a CLIA waiver. In several jurisdictions and in certain settings, barriers to rapid testing exist. In addition, there are insufficient resources provided to states to fully implement their use.

Perinatal Prevention

Perinatally acquired AIDS cases have decreased dramatically, due in large part to HIV testing among greater numbers of pregnant women and their subsequent treatment. In 2003, the CDC reported only 152 new cases of perinatally transmitted AIDS. This represents an 84 percent decline from a high of 954 new AIDS cases in 1992. Only three states account for over 50 percent of all new perinatal cases reported to the CDC. Twenty-two states reported no pediatric AIDS cases. Perinatal initiatives developed by state and local health departments have contributed to the significant decline in perinatally acquired AIDS cases from the peak in the early 1990s.

Louisiana had three cases reported in 2003. Louisiana requires written consent for HIV testing, which has not been a deterrent in testing pregnant women who are unaware of their statues. We treat each case of perinatal transmission as a sentinel event and follow-up to determine where the woman fell through the cracks in the health care system. We continue to find that the lack of access to prenatal care and fear of seeking care for non-citizens and substance using women remains the primary barrier to eliminating perinatal acquired infections.

The prevention of mother to child transmission is one of our greatest prevention successes. One way to further reduce cases is to provide hospitals serving the un- and underinsured with HIV rapid tests for use in the labor and delivery setting. This would require resources for the rapid test kits as well as training for hospital staff on counseling and administration of the screening test.

Importance of the AIDS Drug Assistance Program

The state AIDS Drug Assistance Program is the largest component of the CARE Act. AIDS Drug Assistance Programs (ADAPs) provide HIV/AIDS-related prescription drugs to uninsured

and underinsured individuals living with HIV/AIDS in the 50 states, the District of Columbia, Puerto Rico, Guam, and the Virgin Islands. ADAPs began serving clients in 1987, when Congress first appropriated funds to help states purchase AZT. In 1990, ADAPs were incorporated under Title II of the newly enacted CARE Act. Federal funding for ADAPs is allocated by formula to states and territories. In FY2006, the federal ADAP earmark was $798 million.

Since the advent of highly active antiretroviral therapy (HAART) in 1996, AIDS deaths have declined and the number of people living with HIV/AIDS has increased markedly. ADAPs have played a crucial role in making HAART more widely available. In a given year, ADAPs reach approximately 136,000 clients, or about 30 percent of people with HIV/AIDS estimated to be receiving care nationally.

ADAP has made an enormous difference in the lives of Louisianans infected with HIV/AIDS. The Louisiana ADAP has 26 drugs on the formulary and a fiscal eligibility of 200 percent of the Federal Poverty Level (FPL). In June 2005, the Louisiana ADAP spent $955,331 for 4,609 prescriptions on behalf of 1,704 clients.

The services provided by ADAPs differ from state to state. Eligibility criteria and other services provided such as diagnostic resistance testing and hepatitis C treatments all differ between states. For example, in FY2005 formularies ranged from 19 FDA approved antiretrovirals (ARVs) to all FDA- approved HIV-related drugs. There is also a tremendous range in eligibility criteria. Eligibility criteria range from 125 percent of FPL in one state to 500 percent FPL in several states. Serving as a the final safety net prescription drug program, the variation between state ADAPs is further exacerbated by the variation in benefits and eligibility criteria of state Medicaid programs.

ADAPs are not entitlement programs; annual federal, and in most cases, state appropriations, determine how many clients ADAPs can serve and the level of services they can provide. In FY2005, state's were dependent on state contributions state contributions and pharmaceutical discounts and rebates to sustain their ADAP programs, as the increase in federal dollars for ADAPs was extremely limited. In FY2005, state contributions totaled $253 million, drug rebates totaled $196 million, Title II base funds contributed to ADAPs totaled $23 million and Title I funds contributed to ADAPs totaled $18 million.

States utilize two types of purchasing systems for mediations with 30 states purchasing drugs directly and 24 purchasing through a pharmacy network and then seek rebates. Louisiana is a direct purchase state. In recent years, HRSA and other agencies have suggested that states who are not currently purchasing through a direct purchase system should switch to such a purchasing method. Lower costs are often cited as a reason to do so. A recent study of California's ADAP found that after calculating mandatory *and* negotiated rebates, prices paid for HIV pharmaceuticals are comparable to those paid by states using direct purchase mechanisms. Direct purchase ADAPs often have additional administrative, dispensing and distribution costs that also must be considered in the total cost when comparing these two purchasing mechanisms. Additionally, there are many factors that states must consider to minimize access barriers when choosing a model for drug purchasing, including the size, geography and

demographics of the populations they are trying to serve. The state's existing health care and pharmacy infrastructure are also key considerations in the model chosen.

ADAPs receive the lowest prices in the country for antiretroviral therapies. In 2003, NASTAD established the ADAP Crisis Task Force to negotiate with the pharmaceutical industry on behalf of all ADAPs. Although the large states had the bargaining power, the Task Force felt it was critical that all ADAPs, large and small, had access to the same prices and discounts. The Task Force has agreements with all eight manufacturers of ARVs (Abbott, Boehringer-Ingelheim, BMS, GSK, Gilead, Merck, Pfizer, and Roche). As a result of this highly successful public-private partnership, the Task Force achieved supplemental discounts/rebates beyond those mandated by the 340B program and price freezes that have resulted in over $300 million in savings over the past three years. The Task Force has also expanded negotiations to makers of therapies to treat opportunistic infections (OIs) and other high cost, highly utilized drugs.

Unexpended Expiring ADAP Funds

While administering ADAP, some states periodically finish fiscal years with small amounts of unspent funds. These amounts, typically ranging from five or ten percent of overall awards, may be requested in the subsequent fiscal year to provide services during that fiscal year. The unspent funds typically result from delays in notice of grant awards from the federal government, timing of the receipt of rebate checks, or other unanticipated fluctuations in spending at the state level. Occasionally, the amount of unexpended funds reaches beyond ten percent of a grantee's overall award for reasons specific to the individual jurisdiction. Louisiana currently has no unexpended ADAP funds.

State AIDS director unanimously agree that expiring unexpended funds must be put back into the CARE Act rather than being returned to the Treasury, as is currently the case. States with excessive and chronic amounts of unobligated funds need immediate technical assistance from HRSA to address issues that hinder a state from spending their award.

Our ADAP proposal outlined below would redistribute unobligated funds from all Titles of the CARE Act back into the ADAP program. Although this would be considered one-time-only funding, it would allow states to provide life saving therapy to individuals in need for a year.

Impact of Medicare and Medicaid

As the payer of last resort, the CARE Act is the safety net under other public programs such as Medicaid and Medicare. ADAPs provide services to persons on Medicaid with insufficient drug coverage, i.e., a limited number of prescriptions per month, and assist clients' cost-sharing to receive full Medicaid benefits. As Medicaid programs are altered from state to state, CARE Act programs must adapt to fill the gaps. The Medicare prescription drug benefit (Part D) added another coverage option for eligible individuals living with HIV/AIDS. ADAPs have been assisting clients enroll in Medicare prescription drug plans and implementing their policies to assist clients with filling any gaps of the Medicare drug benefit. The full financial impact of Medicare Part D on ADAPs will be unknown for sometime. However, it is estimated that ADAPs will save approximately $53 million due during FY2006 as a result of Medicare Part D. This number is expected to rise to $67 million in FY2007.

Challenges Facing ADAPs

Ten years after the advent of highly active antiretroviral treatments, the lives of people living with HIV/AIDS have been greatly extended. Therefore, individuals may remain on ADAP for a lifetime. ADAPs across the country continue to encounter significant challenges in maintaining fiscal stability while adequately serving the growing number of uninsured and underinsured individuals living with HIV. These challenges are even more problematic in states with less expansive Medicaid programs and state ADAPs that are administered solely as a result of federal funding.

As of February 16, 2006, a total of 791 individuals were on ADAP waiting lists in nine states. Nine ADAPs have instituted capped enrollment and/or other cost-containment measures since April 1, 2005. Eight ADAPs anticipate the need to implement new or additional cost-containment measures during the current ADAP fiscal year ending March 31, 2007.

Congress and the President have shown strong support for ADAP. On June 23, 2004, President Bush announced immediate availability of $20 million in one-time funding outside of ADAP to provide medications to individuals on ADAP waiting lists in 10 states (registered as of June 21, 2004). At maximum enrollment, the program served 1,487 individuals. As of February 16, 2006, four individuals were enrolled in the program, which is administered separate from ADAPs by BioScrip, Inc. The program is expected to end in the very near future as funding expires. Funds were not provided to continue the program and states have either enrolled these clients in their ADAP or into pharmaceutical patient assistance programs.

For individuals on waiting lists, states make every effort to ensure that clients are linked to pharmaceutical patient assistance programs. However with inadequate resources to even serve clients, it is difficult to accomplish this task as well. It is extremely challenging to engage in efforts to increase the number of people who are aware of their HIV status if the only thing you have to offer is a waiting list.

Although waiting lists are an indication of an ADAP in fiscal crisis, states use other mechanisms to restrict access to the program including reducing financial eligibility criteria, limiting the drugs that are available through the formulary setting monthly expenditure limits, or setting enrollment or medical criteria limits for access to new medications. Many states often pursue these options rather than instituting a waiting list. Solutions to tackle the ADAP crisis that only address waiting lists are insufficient and unfair to other states in need.

As the approximately 300,000 HIV positive individuals who know their status but are not in care seek treatment or are referred into care, a percentage of these individuals without private insurance or ineligible for Medicaid will seek medications through ADAP. And with the use of HIV rapid testing technology, the ability of states to identify HIV positive individuals will increase. Therefore, reauthorization must address the ability of states to increase access to ADAP, including states in chronic need.

Recommendations for Reauthorization

First and foremost state AIDS directors want the CARE Act to recognize the role of the states in coordinating care and treatment services within the state. Currently, other grantees of the CARE

Act are not required to work with the state and HRSA provides little oversight of their activities to ensure that there is not duplication of services. We are seeking to increase accountability by requiring state and local care delivery coordination. There are proposals before Congress to eliminate the statewide component of the CARE Act and only provide states funds for cases outside of Title I EMAs. This will decrease effective state-wide coordination of services. States are responsible for the care of all citizens with HIV in their state and this responsibility should not be undermined. If the statewide component of the Title II base is eliminated, many statewide mandates would need to be eliminated due to lack of resources and participation of the other grantees in statewide processes. The infrastructure to continue providing vital care and treatment services would also be greatly compromised.

State AIDS directors have two proposals for reauthorization which are reflective of our vision for improved access to HIV care services in the nation: (1) to enhance the availability of ADAP resources and services for persons living with HIV/AIDS in need in all areas of the nation, and (2) to provide additional resources to states with chronically insufficient Title II base funds through a Title II base supplemental grant mechanism.

Increase ADAP Stability

State AIDS directors believe a central goal of reauthorization legislation should be to increase states' ability to provide antiretroviral therapy treatment to people with HIV/AIDS. For the past five years, ADAP expenditures have grown by $100 million each year. We support the inclusion of explicit and increasing authorization amounts for ADAP. While this does not ensure that the appropriators will follow suit, we are committed to working with Congress to secure increased funding for ADAP.

For FY2007, state AIDS directors seek an increase of $197 million for ADAPs to maintain those currently enrolled, to meet the growing demand to enroll new clients, and to strengthen ADAPs to provide PHS recommended drugs. We recommend the establishment of a guaranteed minimum level of new funding to ADAP for use in providing access to HIV/AIDS drugs and care, and to direct a portion of this new funding to states with waiting lists, inadequate formularies and restrictive income eligibility criteria. State AIDS directors recommend that a minimum increase of $60 million be provided annually to support ADAPs. While $60 million does not represent the entire need, this guaranteed funding would enable states to provide treatments to low-income individuals, consistent with U.S. Public Health Service guidelines, while enabling them the flexibility to make formulary decisions based on the financial status of their ADAPs. It also recognizes the importance of state general revenue support of ADAPs. If the money is not appropriated, unexpended funds from all titles of the CARE Act should be used and, if necessary, an equal percentage tap on all CARE Act titles, excluding ADAP, should be taken to sustain ADAPs.

ADAP Supplemental Grants for States in Need

State AIDS directors agree that ADAP Supplemental Grants need to be strengthened and a guaranteed source of funding secured. The ADAP Supplemental should no longer be limited to 3 percent of the ADAP appropriation. Rather, the ADAP Supplemental funding should include the amount appropriated in FY2006, plus 20 percent of the guaranteed $60 million ADAP increase. We recommend that eligibility for the ADAP Supplemental be revised as the current

legislation limits awards only to those states with specific program restrictions in place as of January 2000. State ADAPs operate within a complex and dynamic financial environment; therefore restricting eligibility only to those states with restrictions in place as of January 2000 conflicts with the need to provide additional support for states that meet the definition of severe need today. Furthermore, such restrictions in eligibility do not allow for downturns in state and federal economies, rise in the cost of antiretroviral treatment, or other events that impact program solvency over time.

Accordingly, we recommend eligibility be based on: 1) Gross income eligibility criteria of less than 300 percent of FPL; or 2) Inadequate formulary – lack of coverage of any FDA-approved antiretroviral drugs or the PHS-recommended drugs for the treatment and prophylaxis of opportunistic infections for individuals with incomes less than 300 percent of FPL; or 3) Waiting lists of ADAP applicants with incomes less than 300 percent of FPL. A state would maintain eligibility throughout the authorization period and could become eligible for the supplemental at any time during the period.

In addition, state AIDS directors recommend repealing the overall Title II hold harmless provision (including base, ADAP earmark, ADAP supplemental grants, Emerging Communities, and Minority AIDS Initiative funding). This provision has resulted in the unintended loss of significant funds to the pool of available money for ADAP Supplemental grants to states in severe need.

Elimination of ADAP Supplemental Match Requirement
The legislation requires that states secure $1 in state funds for every $4 in federal funds prior to submitting an application for the grant. Therefore, states that meet one of the eligibility requirements but lack the funds to meet the match have been unable to access the funds. This match requirement has resulted in a loss of funds to several state ADAPs that are in dire need of additional resources. We support the removal of the match requirement for the ADAP Supplemental only, with other state match and maintenance of effort requirements continuing in a reauthorized CARE Act.

List of ADAP Core Medications
State AIDS directors recommend that states provide treatments to low-income individuals consistent with PHS guidelines which allow states the flexibility to make formulary decisions based on the financial status of their ADAPs. We oppose any additional formulary requirements without guaranteed federal funding to accompany them.

The significant range of drug access among states raises concern about disparities in access depending on where individuals live. State AIDS directors recognize the need to address such disparities and the importance of establishing a standard of care available to all ADAP clients regardless of residency. However, we are concerned that establishing a core formulary may actually reduce access by creating a formulary ceiling for states with more expansive formularies. For example, if a state with drugs available to treat HIV, OIs, hepatitis co-infection and treatment side effects faces budgetary challenges, the program may be forced to ramp down to offer only the core drugs as a means of cost-savings. Establishing a core formulary may send

a message to state legislators and appropriators that only the drugs defined in the core formulary are needed to provide comprehensive care to people living with HIV/AIDS.

In addition, requiring a core formulary for ADAPs may cause more fiscal strain for ADAPs with limited formularies. For example, in 2005 Louisiana's ADAP offered only the FDA-approved ARVs on its formulary due to budgetary constraints. If a core formulary were defined to include the PHS recommended drugs for prevention and treatment of OIs, it could potentially force this and other ADAPs, in the absence of additional funding, to reduce enrollment in order to allow access to these additional drugs. States with limited formularies would also be forced to put all their Title II base dollars into their ADAP in order to bring their ADAP up to the floor.

We believe, through an annual guaranteed level of funding for ADAP and the enhancement of the ADAP Supplemental Grants, states will provide access to therapies consistent with PHS guidelines including all antiretroviral medications and highly recommended "A1" OI drugs.

Maximization of Funds for Treatment
State AIDS directors recognize the challenges that HRSA faces in administering the 340B Drug Discount Program as authorized under Section 602 of the Veterans' Health Care Act of 1992. We recommend that the Secretary, through HRSA, provide the Unit Rebate Amount (URA) generated by the Centers for Medicare and Medicaid Services on a quarterly basis with ADAPs utilizing the 340B rebate option in the same manner as it is shared with state Medicaid programs. This will allow ADAPs to determine whether they are receiving the appropriate prices and rebate amounts.

We recommend the CARE Act clarify that states that receive rebates from drug manufacturers resulting from the use of federal funds direct the rebate funds back into their ADAP program.

We also recommend that all CARE Act grantees be required to coordinate purchasing efforts with their respective state's ADAP in order to maximize purchasing power and extend the lowest possible price to all grantees. Coordination should occur unless the grantee is able to demonstrate that it can otherwise obtain lower prices for medications than those available through the state's ADAP.

Technical Fix for Select Territories to Receive ADAP Funds
The HHS Office of Inspector General recently determined that American Samoa, the Marshall Islands, and the Northern Marianas Islands are ineligible to receive ADAP funds and therefore did not receive ADAP funding in FY2006. Although the amount of money is under $10,000, these territories should be eligible to receive ADAP funds as they do from the Title II base. A technical correction is necessary to address this matter.

Increase Capacity of States to Provide Care Services
State AIDS directors believe the current EC provision should be modified to address the disparity of funding between EMA and non-EMA states, and those states with 50% of their AIDS cases outside of the EMA. These areas are experiencing a severe lack of Title II base resources that fund critical primary care and support services. States with chronically insufficient Title II base funds have long wait times for primary care and struggle to meet the

needs of persons in smaller urban and rural areas that lack the density to secure Title I CARE Act resources. State AIDS directors propose new resources be directed to states with epidemics that are not highly concentrated enough to be eligible for Title I funding, through Title II base supplemental grants. Funds would be distributed to non-minimum award states without Title I EMAs and to the two states (Louisiana and Ohio) with Title I EMAs in which 50 percent or greater of their state's cases reside outside of their Title I EMA. The $70 million for the Title II base in the President's budget should be appropriated and directed to these states via formula. If the additional funding recommended by the President is not appropriated, the $10 million currently directed to emerging communities should be directed to these states.

State AIDS directors also recommend that minimum awards for states be boosted to $500,000 to ensure a minimum level of infrastructure and capacity to deliver services is maintained. Minimum awards for territories with a significant numbers of cases should be increased to $200,000 as well.

Emergency Response

The CARE Act and policies of other federal agencies, including CDC, should be altered to allow for flexibility as a result of a natural disaster, such as was experienced with Hurricanes Katrina and Rita. Currently, there is no flexibility to allow for emergency reimbursement of services provided when evacuating ADAP clients seek services in other states. In addition, flexibility on the part of HRSA is necessary. In the case of Louisiana, we continue to struggle to put a program back together and provide services to clients. Since Hurricane Katrina, HRSA and CDC have continued to seek continual administrative reports. The needs of the clients must be paramount over the needs of bureaucracy. In cases of an epic natural disaster, federal agencies should be provided the flexibility to waive administrative requirements as well as the financial match, maintenance of effort, and Women's Infant Children and Youth (WICY) requirements on states.

The Louisiana HIV/AIDS Program thanks the Chairman, Ranking Member and members of the Subcommittee for their thoughtful consideration of our recommendations to revise the CARE Act to increase equitable access to critical CARE Act funded services.

Testimony of Michael Weinstein
President of the AIDS Healthcare Foundation

April 26, 2006
at the Senate Federal Financial Management Hearing

As the President of the largest AIDS organization in the United States I am deeply concerned about the lack of access to HIV medical care for a half a million Americans. As we approach the 25th anniversary of the identification of the first cases of AIDS I am troubled by our lack of progress in treating HIV and controlling the epidemic in this country. Our number one priority in all matters relating to AIDS should be protecting the public health. With half the people who are positive not in treatment including many who do not even know their status we cannot control the spread of this disease nor adequately help the people who have it.

AIDS Healthcare Foundation's primary mission is the medical treatment of HIV in this country and across the globe – serving 32,000 patients. In several of the communities AHF serves HIV patients are dangerously underserved. As an example, Alameda County, which includes Oakland, is only spending ten percent of its Ryan White monies on primary medical care. The Magic Johnson Clinic we operate there is largely unfunded. Specialty referrals are almost impossible to obtain. Despite the fact that the County has declared a state of emergency around HIV much more money is being spent on social services than medicine. At our Magic Johnson Clinic in Jacksonville, Florida the situation is similar.

Ten years after the discovery of the miraculous drug cocktails that have made HIV a treatable illness we are treating HIV as it is the death sentence it was in the 1980s. We reauthorized Ryan White five years ago without making the necessary adjustments to reflect the progress we have made in treating the disease and there are some who would have us do this again this year.

We know what it takes to control this disease. We must identify most of the carriers and get them into treatment. And we must effectively educate the uninfected population. Despite billions of dollars a year in expenditures to combat AIDS we are failing on all counts. One need merely look at the numerous countries both rich and poor that are succeeding where we have failed to understand why. We don't do enough tests. We don't provide enough funding to treat. We are spending too much money on the drugs. We are not putting sufficient responsibility on the infected person to protect their partners.

Until we have treatment readily available to everyone who needs it we will continue to have more and more AIDS cases. Until testing is taken out of the rarified atmosphere of an anonymous test site and integrated into mainstream medical cares in hospitals, clinics and doctor's offices we will not identify many of the people who are positive. Until we tell the drug companies that the US Government will not write a black check for purchasing HIV drugs we will continue to have waiting lists for the AIDS Drug Assistance Program. Until we are honest with people about

the consequences of becoming infected by HIV, which is not the day at the beach the way that the drug company ads portray it as, we will continue to fail to fight AIDS effectively in America.

The solutions are quite simple.

If you want to improve access to care require that the lion's share of Federal dollars be spent treating the disease. We are doing this in Los Angeles. The result is a vast network of outpatient clinics both public and private across the vast geography of Southern California. Alameda County would have the same diversity of treatment options if most of their money were not being spent on food, housing, transportation, case management and everything else.

If you want to find more positives you need to test more people in a fast, convenient and cost-effective manner. Routine testing in health care settings without onerous counseling requirements is the only way to go.

If you want to make drugs more accessible to more patients you cannot pay higher and higher prices for each new generation of drugs, including those that are developed at government expense, thus eating up most of the new money that the Congress has appropriated.

If we identify more people who are positive and get them into treatment the number of new infections will go down. If it goes down below the number of deaths then the

number of people living with HIV will be less each year rather than more.

We need the resolve to put the money where it is most needed to stop AIDS. Rural areas and cities with emerging epidemics must get a bigger piece o the pie. Distributing funds based upon where the epidemic was ten years ago will not help up fight it where it is found today. The people most hurt by this are people of color who represent the overwhelming majority of new cases of AIDS.

Public health and politics are a dangerous mixture. Too many decisions about how to address AIDS have been made on the basis of how one constituency or another must be appeased. This had led to a piece-meal, half-hearted approach that has led us to where we are now. There is no more fundamental function of government than the protection of the public health. I strongly urge the Congress to reauthorize the Ryan White Care Act in a fashion that will protect generations to come from this devastating illness. And I would ask you to take another look at other areas of AIDS spending such as vaccines and research where there is enormous waste of public resources. If these changes are adopted now I am confident that in the United States, as happened in Uganda, that this month I visited for the eighth time, we will have less AIDS down the road rather than more.

Thank you.

QUESTIONS AND RESPONSES SUBMITTED FOR THE RECORD FROM KEVIN FENTON, M.D.

Senate Committee on Homeland Security and Governmental Affairs Subcommittee on Federal Financial Management, Government Information and International Security

Q1: HIV-positive individuals who are unaware of their infection may account for up to 70 percent of all new sexually transmitted HIV infections in the United States, according to a "conservative" mathematical calculation form the CDC published in the June 26th edition of the journal, *AIDS*. If this is indeed the case, shouldn't early diagnosis of all those who are infected be the primary HIV prevention goal of CDC?

A: Reducing the number of new HIV infections through prevention programs for both HIV-infected and HIV-negative persons, remains CDC's primary HIV prevention mission. Since April, 2003, with the launch of the "Advancing HIV Prevention (AHP) initiative: New Strategies for a Changing Epidemic", CDC has increased efforts to help people living with HIV reduce the likelihood of further HIV transmission. A key AHP strategy is to reduce the number of HIV-infected persons who are unaware of their HIV infection status. In addition, in 2006 CDC will be releasing Revised Recommendations for HIV Testing of Adults, Adolescents, and pregnant Women in Health Care Settings to further increase HIV testing. These guidelines seek to make HIV screening routine practice in health care settings to reduce the estimated 250,000 persons who are unaware that they are HIV-infected. CDC also promotes increased use of HIV rapid tests. Pending Congressional budget approval, the President's Domestic HIV/AIDS Initiative will provide funding for rapid testing of nearly 3 million persons in the metropolitan areas most heavily affected by the HIV/AIDS epidemic. These CDC initiatives seek to reduce transmission from HIV-infected persons and to

encourage early testing among persons who are unaware of their HIV infection to link them to treatment and prevention programs as early as possible.

Q2: How many HIV tests would need to be made available this year to effectively identify those Americans living with HIV that do not know they are infected? How many tests, including rapid tests, does the CDC intend to purchase and distribute this year and every of the preceding five years?

A: This is difficult to answer. While health departments report to CDC the number of tests performed in publicly-funded sites, many persons are tested in private physician offices and CDC does not receive data on the number tested in these sites. The President's Domestic HIV/AIDS Initiative, proposed for Fiscal Year (FY) 2007, includes testing in clinical and non-clinical settings to support outreach and testing for nearly 3 million individuals, including more than 600,000 incarcerated persons, and 500,000 injection drug users.

In FY 2006, CDC purchased oral fluid rapid tests at the same overall level ($2,329,800) as FY 2005, less the Congressional rescission and agency enterprise-wide cost reductions. That funding purchased 211,800 tests kits.

Q3: Three years ago, the CDC unveiled its "Advancing HIV Prevention" initiative which recommends routine HIV testing be incorporated into standard medical services, universal HIV testing of pregnant women and newborns, confidential partner notification, and rapid HIV testing available in non-clinical settings. How many states have enacted these recommendations? What is being done to assist all states adopt these recommendations?

A: CDC is striving to ensure that no child is born in the United States whose HIV status (or whose mother's HIV status) is unknown. In 2003, CDC recommended the implementation of the "opt-out" testing approach, in which pregnant women are notified that an HIV test will be routinely included in the standard panel of prenatal tests for all pregnant women, but they can decline HIV testing. Despite these recommendations, prenatal HIV screening is not yet universal and there continue to be women arriving in labor with undocumented HIV status. Studies show that an "opt-out" testing approach results in higher testing rates than an "opt-in" approach (i.e., pregnant women receive pre-test HIV counseling and must provide HIV test consent). Currently, seven states have specifically authorized "opt-out" prenatal HIV screening and one state has authorized "opt-out" for newborn testing.

In 2004, CDC and the American College of Obstetricians and Gynecologists (ACOG) issued recommendations for rapid HIV testing at labor and delivery. Although early diagnosis and treatment is the best way to prevent mother-to-child HIV transmission, rapid testing technology provides an opportunity to identify a women's HIV status during labor. This allows providers to begin antiretroviral treatment for women with newly diagnosed infection and for their infants within hours of birth. CDC worked with ACOG and in November 2005 ACOG published a legislative toolkit for state lawmakers that includes suggested legislative language to require "opt-out" testing for pregnant women. ACOG urges state lawmakers to update laws and regulations to be consistent with the current medical recommendations for prenatal HIV testing that no longer require informed consent and for rapid HIV testing during labor for women with undocumented status.

To further decrease perinatal HIV transmission, CDC is working with partners to promote routine prenatal HIV testing using an "opt-out" approach, develop guidance for using rapid tests during labor and delivery or immediately post

partum, provide training in conducting prenatal testing, and monitor the integration of routine prenatal testing into medical practice.

In addition, CDC's "Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health Care Settings," expected to be published in September 2006, will include important recommendations for public and private-sector health care providers with regard to pregnant women. These include: 1) HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women; 2) HIV screening is recommended after notifying the patient that testing will be done unless the patient declines (opt-out screening); and 3) repeat screening in the third trimester is recommended in certain jurisdictions with high rates of HIV infection among pregnant women.

Q4: What is the average amount of time it takes to complete pre-test counseling for HIV? How does this compare to the average time spent on pre-test counseling for other diagnostics, such as a PAP test?

A: CDC has conducted time-motion studies in a variety of HIV counseling and testing venues. Results from these studies suggest that the mean time spent on pre-test counseling ranges from five to 21 minutes. The findings varied by site. For example, in one hospital setting, mean pre-test counseling time was five minutes, while in another hospital setting, mean pre-test counseling time was 16 minutes, and in a community-based organization setting mean pre-test counseling time was 21 minutes. CDC is not aware of comparable time-motion studies for pre-test counseling for other diagnostics.

Q5: A study reported earlier this year in the *Mayo Clinic Proceedings* found that about twice as many hospitalized patients with HIV could be identified if hospitals conducted routine testing. This conclusion echoes the findings of other studies published since the 1980s. In 1993,

the CDC recommended that clinical facilities with higher than average HIV rates offer routine testing. Yet, the author of this latest study noted that "essentially no one has followed this suggestion." What can be done to make HIV testing routine so more of those who are unaware of their status visiting health facilities can be identified and linked to treatment?

A: A significant mechanism that CDC is using to make HIV testing routine in order to better diagnose and improve linkages to care in health care facilities is the publication of CDC's "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings." These guidelines are based on the most recent research findings, including three analyses published in 2005 which showed that HIV screening in health care settings is cost effective even in settings with an HIV prevalence as low as 0.1%. The guidelines, which are expected to be published in September 2006, are being revised to recommend screening in all health care settings of all persons aged 13-64, without regard to individual risk or the facility's HIV prevalence. They will further recommend including HIV testing as part of the general consent for care; that is, HIV testing should not require separate informed consent. These recommendations are designed to normalize HIV testing, to make it a routine activity in all health care settings (thereby reducing the stigma of being "singled out" for risk-based testing), and to also encourage third-party reimbursement as is routine for other recommendation-concordant screening services.

CDC will also develop a practical guide and model protocol for screening in urgent care settings, and has scheduled a series of six regional workshops to assist facilities (especially in high-morbidity areas) in developing their implementation plans.

Other efforts by CDC to further ensure appropriate incorporation of HIV testing procedures into clinical practice is funding several organizations to facilitate

training and technical assistance for facilities needing guidance. In 2006, CDC funded the National Association of Community Health Centers (NACHC) to provide on-site training and technical assistance to five community and regional centers. These efforts are expected to develop procedural guidance to help CDC operationalize HIV screening and prevention protocols and policies from a programmatic, administrative, and clinical perspective. CDC will provide funding to NACHC in 2007 to develop strategies to disseminate the procedural guidance and to assess the success of the dissemination and the extent of the use of the guide.

Also in 2007, CDC will fund two national medical organizations and the Health Research and Education Trust of the American Hospital Association to promote the incorporation of HIV testing as a routine part of medical care and provide technical assistance to 5-10 hospitals in high prevalence areas to establish, maintain, improve, and/or increase the amount of testing provided in emergency rooms.

Q6: If routine testing is not available in all medical settings, at the very minimum, where should routine testing be available?

A: If routine HIV testing is not available in all medical settings, at the very minimum, routine testing should be available for high-risk persons and for those in acute-care settings located in areas of high HIV prevalence.

Q7: What populations and demographics should be routinely tested for HIV or other STDs?

A: In all health care settings, screening for HIV infection should be routinely performed for all patients aged 13-64. In addition, all patients initiating treatment for tuberculosis should be routinely screened for HIV infection; those seeking treatment for STDs, including all patients attending STD clinics,

should be routinely screened for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavioral risks for HIV infection. Finally, all pregnant women in the United States should be screened for HIV infection.

Q8: Why is providing testing opportunities in non-clinical settings important?

A: Not all persons seek routine care in this country. Of the more than 1 million persons living with HIV in the United States, an estimated 25% are unaware of their infection. Because these persons do not know they are infected, they do not access HIV testing, treatment, and prevention services; consequently, they are at high risk for HIV-related morbidity and mortality, and are also likely to continue engaging in behaviors that may transmit HIV to others. Also some people cannot be reached for HIV testing through health care settings, thus an array of testing strategies is needed to reach people who are unaware of their HIV infection.

Q9: Is there any scientific evidence that routine testing discourages those at risk for HIV from seeking testing or treatment?

A: CDC is not aware of any studies conducted among persons who are at risk to evaluate whether routine testing discourages persons from seeking testing or treatment.

Q10: What are the public health benefits of confidential partner notification, including spousal notification?

A: Partner Notification is a key component of HIV Partner Counseling and Referral Services (PCRS). Through PCRS, sex and drug use partners of HIV-infected persons are informed of their possible exposure to HIV. This is particularly important for those partners who do not suspect that they might have been exposed to HIV. Once informed, the partner can decide to access available HIV prevention counseling and testing services. If not infected with HIV, partners can be assisted in changing their risk behavior, thus reducing the likelihood of acquiring HIV. If the partner is HIV-infected, the partner can be referred to ongoing medical care. In addition, PCRS can be instrumental in identifying sexual and drug-injecting networks at high risk for transmission of HIV or other sexually transmitted diseases. Studies have shown that PCRS is a cost-effective tool for reaching persons at very high risk for HIV infection and is acceptable to individuals seeking HIV testing, HIV-infected persons and notified partners.

Q11: The 1996 Ryan White CARE Act reauthorization contained a requirement that as a condition of federal funding all states "require that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to HIV and should seek testing." The CDC certified all states as complying with this requirement. A review by the HHS OIG concluded in August 1999 that "While States have taken action on their certifications, their efforts do not completely ensure that vulnerable people are always made aware of their possible exposure to HIV. Based in our findings, additional efforts need to be undertaken to ensure maximum notification." According to the recent review, at least two states-Massachusetts and Minnesota-actually require the permission of the infected index patient to notify his or her spouse that they could be

at risk. Clearly this is not a "good faith" effort and, in fact, contradicts the intent of the law which is to ensure unsuspecting spouses are alerted to their risk. Does CDC believe that requiring the consent of the infected index patient to alert a spouse—as required by law—a "good faith" effort? Will the agency reconsider its certification of state compliance if states have laws or practices in place that hinder good faith efforts to notify current or former spouses, as required by law?

A: It is difficult to answer this question without looking at the rest of the regulations and laws of states regarding partner notification or spousal notification. For example, in Minnesota, in cases where an index case is unwilling to inform the current spouse of his or her HIV infection, the situation triggers a duty to warn investigation by the Minnesota Department of Health STD and HIV Section. In 1989, the Minnesota Attorney General's Office informed the Minnesota Department of Health that the threshold information to trigger a duty to warn requires:

"1) **Verification** that the known carrier, 2) **aware** of his or her positive serostatus, 3) **presents a foreseeable risk of harm**, 4) to an **identified** partner who 5) is either **uninfected or whose status is unknown** and 6) **who is unaware of the carrier's status**. Additionally, we should be able to demonstrate that the carrier 7) was given an opportunity to inform the uninfected partner, and 8) has **evidenced either an incapacity or unwillingness to alert the unknowing partner**."

The MDH has used this guidance since 1989 to investigate and take action in those cases where an index case is unwilling to inform a current spouse of his or her HIV infection. Additionally, Minnesota Statute 13.3805, subdivision (1)(b)(3) permits the commissioner of health to disclose the name and HIV status of an individual to another individual who is at risk for infection with HIV, such as a current spouse.

Massachusetts has informed us that spousal notification is handled in the same manner as the notification of any partner of an HIV positive person, and relies primarily on the state Disease Intervention Specialist (DIS) system residing at the MDPH Division of STD Prevention (see http://www.mass.gov/doh/cdc/std/services/hivpn.htm).

Under this procedure, the testing counselor, physician, or other care provider makes an active and supported referral to the regional DIS staff. Preferred practice is to arrange a face-to-face meeting between the index case and the DIS. In all cases the DIS interviews the known positive person, or index case, to determine how many individuals with whom the index case may have engaged in HIV and STD risk behavior and collects the names and contact information of his/her sexual and/or injection drug equipment sharing partners, including his/her spouse. Regardless of the stated preferences of the index case, if this individuals states they have not notified any of these exposed persons him/herself, the DIS has the responsibility and authority to use the contact information provided to make notification to each partner of his/her possible exposure to HIV. Notification is always performed in person, though in the case of failure to physically locate a given individual, the DIS has the option of leaving a discreet notice indicating the need to discuss an important health matter. In all cases, repeated attempts to reach partners are made and the case remains open and active until such contact is made. The identity of the contact information source is never revealed. Therefore, the index does not need to give consent to the DIS to make notification and the DIS needs no consent to proceed with notification.

CDC is currently undertaking a legal review and assessment of state laws, policies, and administrative rules concerning partner counseling and referral services (PCRS), including spousal notification. CDC anticipates this report on the legal environment of PCRS will be available in early 2007.

Q12: Many opponents of routine HIV testing argue that by removing the extensive pre- and post-test counseling, at risk populations will not receive valuable prevention information that could lead to risk reduction. Yet a study published in *The Journal of Acquired Immune Deficiency Syndromes* in January 2002 found that "Compared with first-time [HIV testers], repeat testers were more likely to report recent risk behaviors and to acquire HIV." Based on this data, doesn't it seem that pre- and post-counseling is not necessarily as useful to changing behaviors as some might hope? Additionally, is any professional certification required to be an HIV test counselor?

A: The study referred to was conducted among young men who have sex with men (YMSM) in seven U.S. cities. Results from this study cannot be generalized to the entire U.S. population. Nevertheless, the results among YMSM illustrate the significant challenges faced by HIV counseling and testing programs. CDC continues to support HIV counseling as part of the HIV testing process where feasible, especially post-test counseling of persons who are found to be HIV-infected. Professional certification for HIV counselors is required in 29 states. See Appendix A for a list of states (as of September, 2004) that regulate who can offer HIV counseling.

Q13: You noted that in your testimony that "emerging data suggest that singling out HIV testing is likely to perpetuate the stigma surrounding HIV testing" and that "routine testing also reduces stigma associated with having to disclose behavioral risks." Could you elaborate on these points?

A: Much of our experience with routine testing has come from perinatal HIV testing. The "opt-out" approach to perinatal HIV testing has been shown to reduce anxiety surrounding HIV testing and to substantially increase test acceptance rates. Under the opt-out approach, women are notified that an HIV test will be included in a standard battery of prenatal tests and procedures and that they may refuse testing. Increases in prenatal HIV-testing rates have been noted in states that shifted from an opt-in approach to an opt-out approach and were probably associated with a greater likelihood that woman were offered HIV testing during prenatal care. Furthermore, data from CDC's Perinatal Guidelines Project indicated that the majority of women will accept HIV testing if it is recommended by their health-care provider *(MMWR, 51(45);1013-1016).*

Q14: In your testimony you pointed out that "about half of the 50 states require informed written consent before an HIV test can be conducted" and that "at the federal level, the Ryan White CARE Act requires counseling before testing of HIV disease." Are there any other medical diagnostics that are regulated in a similar manner?

A. Genetic testing and newborn screening are two examples of types of diagnostics that are regulated in a similar manner at the state level. Over half of the 50 states have legislation that requires informed consent or counseling for genetic testing. According to the National Conference of State Legislatures, 16 states require informed consent for a third party either to perform or require a genetic test or to obtain genetic information, and 24 states require informed consent to disclose genetic information. (See http://www.ncsl.org/programs/health/genetics/prt.htm for additional information.). Nineteen states and the District of Columbia require those involved in newborn

screening to provide specific educational information to the parent or guardian before screening takes place.

Q15: In your testimony, you list a number of legal barriers to early diagnosis that currently exist, including who can order an HIV test, pre-test counseling and written consent for testing. Could CDC provide the Subcommittee a state by state listing of these specific barriers?

A: Most states regulate who can provide HIV testing, HIV counseling and Partner Counseling and Referral services (PCRS). A comprehensive summary of state statutes as of September, 2004 (Appendix A) is included for your information.

Q16: Substance abuse continues to be a significant factor driving HIV infection in some communities. How many people nationwide currently require treatment for substance abuse? "Do we know how many Americans are on waiting lists for substance abuse treatment? Does lack of treatment on demand for addiction deter those in need from successfully kicking the habit? What prevention initiatives is the CDC currently supporting to address HIV risk among substance abusers?

A: Information on the number of persons requiring drug treatment or on waiting lists for treatment is not available at CDC. Such data may be available through the Substance Abuse and Mental Health Services Administration (SAMHSA).

As of 2004, injection drug users (IDUs) accounted for 24% of all persons living with AIDS. Comparing rates of HIV/AIDS diagnosis during 2001-2004 in the 33 states with long standing HIV/AIDS surveillance reveals substantial racial and

ethnic disparities. Among male IDUs, the rate for African Americans was 26.9 per 100,000 population, compared with 1.7 for whites, 12.0 for Hispanics, 1.6 for Asian/Pacific Islanders, and 2.7 for American Indians/Alaskan Natives. Among female IDUs the rate for African Americans was 14.2 per 100,000 population, compared with 1.0 for whites, 4.8 for Hispanics, 0.6 for Asian/Pacific Islanders, and 2.2 for American Indians/Alaskan Natives.

To address these high rates and racial and ethnic disparities among IDUs, 58% of directly-funded CBOs provide evidence-based prevention interventions serving sexually active IDUs and their partners. IDUs are one of the three groups at high risk for HIV infection included in the National HIV Behavioral Surveillance System to monitor risk behaviors, testing, and use of prevention services. Data collection for IDUs occurred in 2005 and the data are being analyzed.

QUESTIONS AND RESPONSES SUBMITTED FOR
THE RECORD FROM DEBORAH HOPSON

Health Resources and Services Administration

1. What was the total amount of unobligated Ryan White CARE Act funding that was returned to the Treasury on March 31? What is the next date that unobligated CARE Act funds will be returned to the Treasury?

   No money was returned to the Treasury on March 31. Money is returned to the Treasury at the end of the fiscal year. The unobligated funds from 2001 will be returned to the Treasury on September 30, 2006. The unobligated funds from 2002 will be returned September 30, 2007 and so on.

2. If Congress does not reauthorize the Ryan White CARE Act before October 1 of this year, could you explain how funding to states that have failed to enact a names based HIV reporting system would be affected?

   The 2000 CARE Act Amendments require the Secretary to utilize HIV disease data in funding formulas for FY 2007. CDC will implement the provisions contained in the law as enacted for the reauthorization of the Ryan White CARE Act. CDC is committed to assisting states to move from code-based to name-based surveillance systems as quickly as possible.

3. GAO concluded that "The ADAPs with waiting lists may not represent all eligible individuals who are not being served and "whether any ADAP turned away individuals who would have been eligible without establishing a waiting list." If this the case, how do we know that there aren't more eligible patients that are going with treatment? What is your best estimate of the number of Americans living with HIV who are not receiving regular treatment?

   The Administration has proposed a $70 million increase in funding for the Ryan White CARE Act for FY 2007 that would be used to bridge the existing gaps in coverage for Americans waiting for life-saving medications. These funds would help the States end current waiting lists and help support care for additional patients.

   Insofar as estimating the number of persons eligible but not receiving treatment, there are no national data available to adequately answer this question.

4. GAO found that "All of the 25 ADAPs that used the 340B direct purchase option reported prices to HRSA that were higher than the 340B price for at least one of the top 10 drugs" and that "Of the 27 ADAPs that used the 340B rebate option to purchase drugs in 2003, all except 3 ADAPs reported paying drug prices that were higher than the 340B prices for many of the top 10 drugs." GAO noted that "Three ADAPs reported prices that were more than then the 340B price for at

least 8 of the 10 drugs—Delaware (10), Oklahoma (9), and Kentucky (8)." As you know, both Oklahoma and Kentucky have waiting lists and other restraints on ADAP coverage and Kentucky attracted national attention recently when several patients on its ADAP waiting list passed away. Considering the desperate financial state of many ADAPs, why isn't HRSA doing more to ensure that ADAPs are getting fair drug prices?

HRSA's Office of Pharmacy Affairs (OPA) is tasked with administering the 340B program. OPA does not have the legal authority to share legally protected pricing data with ADAP grantees or other covered entities. With greater pricing transparency, grantees could know whether they were charged the 340B ceiling price by their suppliers. The President's Budget Request for FY 2007 includes resources for OPA to develop a Web-based tool for entities to use to assess the price of a market basket of drugs purchased at the 340B prices that will protect confidential pricing data for individual drugs. OPA does not have the resources to make manual assessments and comparisons of price files that ADAPs and other covered entities may submit.

5. GAO reports that "HRSA further states that it lacks the resources to conduct a comprehensive price comparison" for drugs purchased by ADAPs. Why can't HRSA simply share the 340B prices with ADAPs so each can check the prices they are paying themselves?

HRSA is restricted from revealing the prices by confidentiality agreements between the manufacturers and the Federal government. Because of the statutory prohibition on release of 340B pricing data, OPA is only able to indicate that prices paid by ADAPs are within a percentage range of the 340B ceiling price. In response to recommendations made by the Office of Inspector General, HRSA has proposed and included in the Administration's FY 2007 Budget Request the creation on the OPA Web site of the capacity for 340B covered entities to compare the price of a market basket of drugs without sharing statutorily protected pricing data. HRSA has requested that drug manufacturers voluntarily share their 340B pricing files with the OPA and the 340B Prime Vendor. HRSA will compare the drug companies' prices with those reported by major drug wholesalers for compliance with prices computed by OPA. With permission of the drug manufacturers, the 340B drug price file will be posted on the Prime Vendor's pass-word protected Web site. Covered entities, including ADAPs, can compare prices at the time of purchase.

6. Do you expect significant numbers of ADAP recipients to be eligible for the Medicare prescription drug benefit? How will Medicare Part D impact ADAP waiting lists?

ADAPs are requiring clients who are Medicare-eligible to participate in the Medicare prescription drug plan benefit (Part D). While individual participation in Medicare's drug plan is voluntary, the CARE Act is the payer of last resort for HIV/AIDS care and treatment.

Since Medicare is a Federal health benefits and entitlement program, the CARE Act payer of last resort requirement applies. Grantees must require Medicare-eligible ADAP clients to enroll in the prescription benefit.

This does not mean that ADAPs must drop Medicare Part D eligibles. States have flexibility in determining their eligibility criteria as well as policies with respect to covering the Part D out-of-pocket costs of ADAP clients.

HRSA expects and strongly encourages ADAPs not to disenroll any ADAP clients-including Medicare-eligible beneficiaries without first making sure that they have a viable option for continuing their antiretroviral drug coverage.

CMS estimates about 60-70,000 persons living with AIDS (PLWAs) are in the Medicare Part D prescription drug program. CMS does not have solid data on those who have HIV but not AIDS. ADAPs serve PLWHAs who are HIV-infected while PLWHAs who qualify for Medicare usually are disabled (have an AIDS-defining disease) and have to wait 29 months for Medicare coverage.

The impact on the ADAP waiting lists will depend on the final estimates of those who enrolled in Medicare Part D by the May 15, 2006 deadline.

7. Substance abuse continues to be a driving force behind the HIV/AIDS epidemic. How does untreated substance abuse hinder efforts to treat those who are infected and how much does the CARE Act spend on substance abuse annually? How does this amount compare to the annual amount spent on other services such as housing, case management and planning?

The relationship between drug abuse and HIV/AIDS is complex. First, injection drug use is not the only way in which drugs contribute to the AIDS epidemic. Second, not only heroin, but also other opiates, cocaine, amphetamines, and sedatives all may be abused through injection and spread HIV infection among those who share paraphernalia. Buprenorphine is a new addiction therapy in the United States and many of the clinicians using it so far have been involved in the clinical trials that found that it safe and effective. The HIV/AIDS Bureau (HAB) staff has undertaken several projects related to buprenorphine, including a Special Projects of National Significance (SPNS) initiative that is examining model demonstration projects for integrating buprenorphine treatment into HIV primary care settings. In addition, Title I funds may be used to provide a continuum of care for persons living with HIV disease to including substance abuse and mental health treatment and Title III services also provide attention to

other health problems that occur frequently with HIV infection, including tuberculosis and substance abuse.

Because active drug use is associated with poor adherence to antiretroviral medication regimens, addiction therapy appears to improve clinical outcomes in HIV-positive addicts. Experts overwhelmingly agree that treating drug addiction in people who are HIV-positive can improve outcomes for both diseases.

The Regional AIDS Education and Training Centers Program (AETC) is supporting training that target Ryan White CARE Act funded providers and staff on HIV/AIDS and mental health co-morbidity services and treatment. The AETCs are utilizing mental health training curricula developed by the following professional associations: American Psychological Association, the American Psychiatric Association and the National Association of Social Workers to train on three specific topic areas (1) ethics, (2) neuropsychiatry, and (3) mental health and substance use. The AETC National Resource Center is also providing the logical support and coordination of these training exchanges.

Data on the allocation of funding by type of service are available for Title I and Title II CARE Act programs. As seen below, we have compared the allocations of program funding for substance abuse treatment, oral health care, mental health care, case management, housing services and planning by Title.

Service	***Title I***	***Title II***	***Total***
Substance Abuse	*$37,317,798*	*$2,705,250*	*$40,023,048*
Oral Health	*$19,093,963*	*$7,231,713*	*$26,325,676*
Mental Health	*$29,927,874*	*$6,709,441*	*$36,637,315*
Case Management	*$73,576,436*	*$60,382,395*	*$133,958,831*
Housing	*$31,102,724*	*$5,439,888*	*$36,542,612*
Planning	*$15,995,913*	*$18,106,327*	*$34,102,240*

8. Treating patients co-infected with HIV and hepatitis B or C poses unique challenges to both doctors and patients. What efforts are HRSA or other HHS agencies making to assist health care providers recognize and treat co-infection?

Care and treatment for Hepatitis coinfection has been successfully integrated into several different venues, including CARE Act-funded clinics. Access to HCV treatment as of December 2005 was covered under 20 State ADAPs which provide access to interferon and ribavirin; 17 also cover pegylated interferon. Many ADAPs also provide access to drugs to manage the side effects of HCV treatment along with vaccinations for HAV and HBV. The AETCs Mountain Plains center is designated as a HIV/Hepatitis C Center of Excellence. HRSA's HIV/AIDS Bureau is also currently working on a booklet, Care and Treatment for

Hepatitis C and HIV Coinfection: Expanding Access through the Ryan White CARE Act, to assist CARE Act grantees in responding to HIV/HCV Coinfection.

9. In June 2004, the President made available $20 million in funds from sources other than the CARE Act to provide HIV/AIDS drug assistance to individuals then on ADAP waiting lists in ten states. The President's ADAP Initiative (PAI) greatly reduced the number of Americans on waiting lists but the number is again rebounding. Have these funds been exhausted? Are there plans to identify additional funds that could be used to continue this initiative to care for patients on ADAP waiting lists? What else can be done with existing funding to alleviate ADAP waiting lists?

   To date approximately 1,793 clients were served in the eight states which participated in the program. (Note that two states, Colorado and South Dakota never participated in the PAI. They received additional funds from their state and eliminated their waiting lists prior to program start.)

   The funds remaining are slightly less than $859,000 and clients from four states are currently enrolled in the PAI. They will continue to receive medications until the funds are exhausted. There are no plans to seek additional funds to continue this effort.

10. I understand that HRSA recently disqualified the Marshall Islands, the Northern Marianas and American Samoa from ADAP eligibility. Could you explain this decision and how many patients receiving ADAP in these areas will be affected?

    In its recent review of the CARE Act, the GAO discovered a drafting oversight in the current statute. In reviewing the GAO's findings, HRSA/HAB reluctantly agreed that the language in the current CARE Act statute, 42 USC 2618, excludes from the ADAP earmark award eligibility the five Pacific jurisdictions which were added to the program in the 2000 program reauthorization.

    Only three of the jurisdictions received ADAP awards between 2001 and 2005, and none had more than 2 estimated living cases of AIDS.

11. Are their regional variances in the capacity of the HIV medical workforce (including physicians, nurse practitioners and physician assistants) that affect the ability of Ryan White-funded clinics to meet the medical needs of people with HIV/AIDS that qualify for Ryan White services? Are their significant differences in waiting times for appointments, distance traveled to access medical care, and the ability of the clinic to retain or recruit medical staff?

    HRSA monitors health professions shortage areas in order to improve the health status of the population by providing national leadership in the development,

distribution, and retention of a diverse, culturally competent health workforce that provides the highest quality care for all. Data collected on regional variations in the healthcare worker supply does not specifically address variations within the HIV-related medical workforce realm.

12. Are patients with HIV/AIDS eligible for CARE Act services required to travel extraordinary distances in certain regions of the country to access treatment at Ryan White-funded clinics? Does the distance that people eligible for Ryan White services need to travel to access Ryan White-funded treatment vary significantly by region of the country?

The Ryan White CARE programs work with cities, states, and local community-based organizations to provide services that enhance access and address barriers to care. Under Title II, comprehensive planning provisions require states to develop strategies to eliminate barriers and disparities in access. Under Titles III and IV of the CARE Act, grants are available to urban and rural areas to provide HIV/AIDS services. Title III funds 453 community-based primary care clinics of which 133 serve rural communities. We are not aware of any studies that specifically assess distances traveled by eligible persons who receive Ryan White CARE Act services.

13. Are there significant regional differences in the ratio of Ryan White medical providers to Ryan White eligible patients in a given catchment area? Are there significant regional variances in the health care financing available for HIV/AIDS medical treatment? Are regional differences in HIV medical workforce capacity exacerbated by funding decisions that are made at the local or state level by Ryan White-funded grantees? If regional differences in the capacity of the HIV medical workforce are identified, what can and should be done to address these disparities?

HRSA has not conducted any analyses, nor are we aware of any research that has been done externally related to regional differences in the ratio of Ryan White medical providers to Ryan White eligible patients in a specific catchment area and funding decisions regarding HIV medical workforce capacity.

With regard to regional variations in healthcare financing across the States, many of the programs that provide care to people with HIV have significant variation in eligibility benefits and other program components. For example, the IOM's "Public Financing and Delivery of HIV/AIDS Care" report (2005) found that in "states with less generous Medicaid programs (e.g., states with limits on the number of prescriptions filled per month or states with lower income eligibility thresholds), low-income people with HIV may have to rely on other programs to fill the gaps or may not have access to needed services."

Additional descriptions of variations in healthcare financing across the States are reflected in Table D-2 (Pgs 284-290) of the aforementioned report.

QUESTIONS AND RESPONSES SUBMITTED FOR THE RECORD FROM MARCIA CROSSE

1. **Your report analyzed only prices paid by ADAPs. Do you know if other CARE Act titles are receiving the best drug prices?**

   We do not have HIV/AIDS drug price data for any non-ADAP entities under the other CARE Act titles.

2. **You found that of the federal health programs you looked at, that Medicaid is generally paying the highest price for AIDS drugs. Would GAO analyze the prices Medicaid is paying for medications for other health conditions compared to 340B prices and other federal programs and report back to Congress on your findings?**

   This analysis was beyond the scope of our report's review, however, we would be available to work with Senator Coburn's staff to discuss a request for a separate GAO review.

3. **You noted in your report that "nine ADAPs reported receiving Title I fund transfers from the EMAs in their states." Of those states currently with ADAP waiting lists, do any contain EMAs that could contribute funds to alleviate the current waiting lists?**

   Our most recent ADAP waiting list data is for fiscal year 2004 that we used in our report. Of the 14 states with ADAPs that had waiting lists ranging between 2 and 12 months during fiscal year 2004, only Colorado (Denver) and Oregon (Portland) had EMAs. Only Colorado's EMA (Denver) transferred Title I grant funds—$560,254—to its state ADAP in FY 2004. During fiscal year 2004, Colorado reported having an ADAP waiting list for 10 months and Oregon reported having one for 2 months. The decision to transfer Title I funds to an ADAP is a decision made by the EMA.

4. **Congress created the ADAP Severe Need grants to assist states that had difficulty providing access to AIDS drugs to eligible patients. What states with ADAP restrictions that are eligible for this additional assistance did not apply?**

   In our report, we used ADAP Severe Need grant data for fiscal year 2004. In fiscal year 2004, there were 25 grantees (24 states and Puerto Rico) eligible to receive Severe Need grants. To be eligible, these grantees' ADAPs must have met one of the four following eligibility criteria as of January 1, 2000:
   - Limited the eligibility of ADAP enrollees to those with incomes at or below 200 percent of the federal poverty level.
   - Limited the number of ADAP enrollees by using medical eligibility restrictions.

- Limited the number of antiretroviral drugs covered in its drug formulary.
- Limited the number of opportunistic infection medications to less than 10 in its drug formulary.

Of the 25 eligible grantees, 9 did not apply because they did not provide the required 25 percent match. According to HRSA, grantees can provide funds or in-kind services to meet the matching requirement. The 9 grantees were: Alaska, Arizona, Iowa, Maine, North Dakota, South Dakota, Tennessee, Utah, and Vermont. Among the 9, Alaska, Iowa, and South Dakota had ADAP waiting lists in fiscal year 2004.

5. **Based on the data GAO collected, how were the rates of HIV testing of pregnant women affected by enactment of laws requiring mandatory HIV testing of newborns?**

We did not collect data that would definitively show a cause and effect relationship between the enactment of state laws requiring HIV testing of newborns and the rates of HIV testing of pregnant women. However, as we stated in our report, officials in the two states with laws that require HIV testing of newborns—Connecticut and New York—told us that their laws resulted in an increase in the number of pregnant women tested for HIV. A Connecticut official said that the rate of HIV testing of pregnant women before the state's mandatory testing law passed was about 25 percent and since the law was enacted in 1999, the testing rate has increased to 90 percent or more. Data presented on prenatal HIV testing in New York show that the testing rate increased from 64 percent in 1997, when New York's newborn testing law was enacted, to 95 percent in 2003.

6. **CDC estimates that 280 to 370 HIV-infected infants are born in the U.S. every year. Yet your report found that "few states collect the data needed to determine statewide perinatal HIV transmission rates." If this is the case, is it possible that the actual number of babies being born with HIV could be much higher?**

There are two separate data issues raised in the question—the statewide perinatal HIV transmission rate and the actual number of HIV-positive newborns. In order to calculate the rate of perinatal HIV transmission, data are needed on both the number of live births to pregnant women who tested positive for HIV and the number of newborns that tested positive for HIV. Our finding that few states collected data needed to determine statewide perinatal HIV transmission rates for 2002 was based on data reported by the eight states we contacted. The majority of these states—5 of 8—did not have statewide data for 2002, on the number of live births to pregnant women who tested positive for HIV, which was needed to calculate perinatal transmission rates. However, some of the states we contacted collected information on the number of HIV-positive newborns. Six of the eight

states reported that the number of newborns that tested HIV-positive declined in their state in 2002 compared to 1997. The data GAO collected from the states we contacted are not sufficient to calculate the actual number of babies being born with HIV in the U.S.

7. **GAO found that two states—Massachusetts and Minnesota—require the written consent of an index patient to confidentially notify a partner of possible HIV exposure. The Centers for Disease Control and Prevention (CDC) disputes this finding and claims that both states allow current and former spouses of infected patients to be notified without the consent of the index patient. Who is right and who is wrong?**

Our findings were related to partner counseling and referral services (PCRS) in twelve states under which partners (including spouses) of HIV-infected persons are routinely notified of their possible exposure to HIV. Ten states had statutory or regulatory provisions that explicitly required or permitted PCRS personnel discretion when an individual tested positive for HIV to notify partners of their possible exposure to HIV without the infected individual's consent. Some states also had provisions permitting states to warn anyone who may have been exposed to HIV or other diseases in limited circumstances, but these provisions were not identified by PCRS personnel as the basis for routine partner notification.

It remains our understanding that Minnesota has no provision that explicitly requires or permits PCRS personnel to notify partners of possible exposure to HIV without consent, but it does have a more limited provision. Specifically, the commissioner of health may take legal action against a disease carrier who is a health threat to others, as defined by statute, and engages in certain behavior. If the court finds the allegations proven by clear and convincing evidence, it may grant an order permitting partner notification without consent. We were told that such actions have been taken approximately twice in the past twenty years, and therefore it does not appear to provide a basis for routine partner notification.

A Massachusetts law prohibits health care facilities, physicians and health care providers from testing anyone for HIV, disclosing HIV test results, or identifying anyone tested for HIV without written consent. Based on consultation with PCRS personnel, we understood this law to be an obstacle to their notifying partners without consent. We have been told by PCRS personnel recently, however, that this law does not apply to them nor prohibit PCRS, health care facilities, physicians or health care providers from notifying partners (including spouses) of possible exposure to HIV without the infected individual's consent so long as they do not reveal the name of the infected person.

We are not aware of case law on this point so this interpretation of the state law prohibiting disclosures related to HIV has not been tested. In addition, as of July 20, 2006, it is not clearly reflected in the Massachusetts Department of Public Health's Web site. For example, it advises that "[s]ome states allow, but do not

require, physicians to inform unsuspecting and exposed partners. Even if 'Duty to Warn' motivated notification is allowed, many physicians will still ask the Health Department to do this task. This is not possible, since the voluntary consent of the infected person is required for public health partner notification." http://www.mass.gov/dph/cdc/std/services/stdwar.htm

Although Massachusetts is revising its reporting requirements, health care facilities, physicians and health care providers are currently required by regulation, to report positive HIV test results under a "non-name reporting system" expressly to comply with the Massachusetts law discussed above. As a result, PCRS personnel may not learn the names of HIV-infected persons and their spouses except when an infected person provides or consents for others to provide such information to them. In any event, Massachusetts has no statutory or regulatory provision that explicitly requires or permits PCRS personnel to notify partners of their possible exposure to HIV without consent.

QUESTIONS AND RESPONSES SUBMITTED FOR THE RECORD FROM M. BETH SCALCO

Does the New Orleans EMA contribute to your state ADAP Program? Would support from Title I enable you to expand your formulary or increase access to ADAP? Would patients living with HIV/AIDS in your state –and other states- benefit from more coordination between different CARE Act Titles? How can we ensure better coordination?

During the ten years that Louisiana has operated a State ADAP, the New Orleans EMA made contributions to ADAP during three grant years. These allocations have ranged from $166,000 to $339,631, and all funds have been utilized to provide antiretroviral medications to ADAP-eligible individuals living within the New Orleans EMA.

Additional support from the Title I EMA would allow the State ADAP to potentially expand the formulary or increase access to the program, but only if these allocations were consistent from grant year to grant year. Sporadic and random allocations will not enable to the program to provide consistent services over the course of time, and such actions make the process of planning and allocating scarce resources difficult—if not nearly impossible. Current utilization of the State ADAP in the greater New Orleans metropolitan area is approximately $450,000 per month, which is down from an average of $675,000 per month prior to Hurricane Katrina.

Clients residing in areas outside of the Title I EMA rely on the Louisiana ADAP for assistance with their medications. Louisiana ADAP is restricted to those living at or below 200% poverty and has a formulary of only 25 medications. However, if an individual resides in the New Orleans EMA they are eligible for assistance with medications through Title I if they are living at 201% to 400% of poverty. Title I clients also have access to hundreds of medications that ADAP is unable to cover due to limited resources. If Title I made a consistent contribution of at least 10% ($700,000) to ADAP, access could be expanded and a more equitable distribution of medications could occur across the State.

Patients living with HIV/AIDS in Louisiana would benefit from increased coordination between the CARE Act Titles, but the State, as the Title II grantee, has found that such an effort is very difficult to implement under current authority. While all Title participation and coordination is required for the generation and ratification of the SCSN and the Title II HIV Comprehensive Plan, in reality that participation from other Titles is limited and is often only nominal. Furthermore, it appears that these documents are then not consulted when designing, implementing or monitoring other CARE Act-funded programs. Unfortunately, though there is a requirement to participate in these endeavors and for all Titles to propose activities consistent with the plan, there is no consequence when a grantee does not. Nor is there adequate oversight or action on the part of HRSA to assist with grantees that do not actively participate, coordinate, or abide by the SCSN.

There is often significant duplication of services between Title III providers that are located in the same geographic area, and the disparity between the level of services

offered in the New Orleans EMA and those offered in the rest of the state is significant. Failing grantees are not frequently monitored or asked to implement corrective actions, and are very rarely de-funded. While greater coordination among CARE Act grantees would be an optimal goal, such responsibility *without true authority* will continue to result in lack of coordination and duplication. In addition, the Title II Program does not receive adequate information about which organizations have been funded in the State, the level of funding, or the services the grantee has been funded to provide. Nor is the State consulted on funding decisions. This has resulted in agencies being funded by HRSA that have been banned from doing business with the State and are not ideal providers of HIV services.

Louisiana has had a names based HIV reporting system since 1993. Over the past 13 years, has the state experienced any breach of confidentiality with this system? Is there any evidence that this reporting system has deterred at risk populations from seeking testing?

Both HIV and AIDS have been reportable by name since they were integrated into the state's Sanitary Code as reportable conditions—AIDS in 1984, HIV in 1993. We are not aware of any breaches of confidentiality with the state's HIV/AIDS surveillance system. We also do not have any evidence that the state's name-based reporting system deters at-risk populations from seeking testing. For those who may be reticent to test confidentially, anonymous testing continues to be available through the State's publicly funded HIV Counseling and Testing Program.

HIV-positive individuals who are unaware of their infection may account for up to 70 percent of all new sexually transmitted HIV infections in the United States, according to a "conservative" mathematical calculation from the CDC published in the June 26th edition of the journal, AIDS. What percentage of those living with HIV in Louisiana do you estimate are unaware of their status? Does Louisiana intend to adopt the CDC's "Advancing HIV prevention" initiative that recommends making HIV testing a routine component of medical exams?

It is estimated that between 5,035 and 7,135 persons in Louisiana are unaware of their HIV infection. Louisiana is committed to and has made great strides in adopting the CDC's "Advancing HIV Prevention" (AHP) initiative. Although Louisiana supports the concept of making HIV testing a routine component of medical exams, we do not have the fiscal resources to implement this protocol. Our intention is to work with private providers and insurance companies to integrate HIV testing as a routine component of medical exams. With our current level of resources, we offer HIV testing as a routine component of medical exams in publicly-funded pre-natal clinics and STD clinics, and to persons at increased risk in other medical settings. In adopting CDC's AHP, we have expanded testing in correctional facilities, emergency rooms, and through partner counseling and referral services. Testing through these venues has resulted in higher positivity rates than testing in more traditional settings.

GAO found that Louisiana experienced an increase in perinatal HIV transmission between 1997 and 2002. Louisiana has an "opt in" approach to HIV testing of pregnant women. What percentage of pregnant women is not screened for HIV in Louisiana each year? Have you considered updating your state policy making HIV testing of pregnant women routine with the right to "opt out" or requiring testing of newborns whose mothers' HIV status is unknown, as recommended by the CDC?

The GAO report requested perinatal HIV transmission data from two specific years—1997 and 2002. While 1997 represented the year with the lowest rate of transmission and 2002 represented the year with the highest rate of transmission during that five-year period, the rates did not necessarily increase. Rather, the annual rates of transmission have remained relatively stable—between 4-6% each year. For births in 2003, the program currently estimates that approximately 3% of the perinatally exposed children were ultimately infected.

At this time, state law mandates that HIV testing, including those conducted during pregnancy requires informed consent. The Louisiana Office of Public Health HIV/AIDS Program is currently exploring the legislative changes that would be required, as well as the feasibility and the potential impact of adopting an "opt out" approach to HIV screening during pregnancy and/or screening of newborns for children born to women without documentation of HIV status at the time of delivery.

Louisiana does not have information about testing among all pregnant women in the State because the program does not have the authority or a system to report or collect that information. Some information about the general population may soon be available through the Louisiana Pregnancy Risk Assessment and Monitoring System (PRAMS), a national population-based risk factor surveillance system funded by the Centers for Disease Control and Prevention (CDC) designed to identify and monitor certain maternal behaviors that occur before, during, and after pregnancy. Louisiana PRAMS recently added a question to the survey that specifically asks if the woman was tested for HIV during pregnancy. According to Louisiana's HIV/AIDS surveillance data, most delivering women with HIV who are reported to the surveillance system are diagnosed prior to or during pregnancy or delivery (98% in 2002). Through the state's perinatal HIV prevention efforts, the Louisiana Office of Public Health HIV/AIDS Program actively promotes prenatal HIV screening during prenatal care as the standard of care and posits that failure to offer testing is a breach of duty.

Ensuring Early Diagnosis and Access to Treatment for HIV/AIDS
Subcommittee on Federal Financial Management
Senate Homeland Security and Governmental Affairs Committee

Michael Weinstein, AIDS Healthcare Foundation

(a) How many clients does AHF provide HIV testing and counseling to every year?
12,500 on average, with 2% testing positive.

(b) In California, on average how long does it take to provide pre-test counseling?
20 to 40 min

(c) Is this typical of pre-test counseling for other medical conditions?
No, this is not typical for other medical conditions. There is virtually no other disease or condition, for which there is a test that has such an extensive and required pre-test counseling session.

(d) Does this unusually lengthy pre-test counseling requirement deter providers from offering or patients from receiving HIV testing?
We believe the lengthy pre-test counseling requirement is a deterrent for patients receiving the test, especially for repeat testers who have undergone the extensive counseling on numerous occasions. While the requirement prevents providers of the test from offering more tests within a certain timeframe, it does not deter from offering the test.

Are there other legal barriers that hinder efforts to promote early diagnosis?
There are a number of other barriers to early diagnosis of HIV such as issues with partner notification and the fact that couples cannot undergo testing and counseling together. Another impediment is the large percentage of anonymous testers that test positive and then cannot be found to provide information to. In the arena of HIV, civil rights and prudent public health policy, with 25 years of experience with HIV, we have arrived at a time when confidential testing has become more appropriate, in order to be more efficient and effective in this battle.

Should the number of representatives on Title I planning councils from organizations that receive CARE Act funding be limited? Is there any conflict of interest in such an arrangement?
In order to remove conflict of interest in Title I planning councils, participation by organizations that receive CARE Act funding should be limited. This encourages and facilitates greater community involvement and input on the quality of HIV care and services in the area.

GAO found that ADAPs may not be receiving the best possible prices for AIDS drugs and as a result we may not be getting the maximum return on federal funding for ADAP. What is your view of AIDS drug prices based upon your experience as the largest HIV/AIDS specialty medical provider in the U.S.?
The soaring cost of prescription drugs is an issue that is at the forefront of American politics and news. In federal, state and local governments across the country, legislation ad policies have been set forth to combat these rising costs; tackling the issue from many directions, yet

never seeming to make much progress. Advocates maintain that the pharmaceutical industry is virtually unregulated and charges inflated prices that Americans have no choice but to pay. The industry claims the price of drugs reflects the high costs associated with researching, developing and manufacturing new treatments. Whether one identifies with the advocate or the industry point of view, it is clear that the high cost of prescription drugs prevents millions of people from accessing much needed, and often lifesaving, medicines.

The attached paper examines methods governments, public and private entities, and health care advocates can pursue to establish and access lower priced prescription drugs, especially with respect to antiretroviral drugs (ARVs). The paper provides background on current federal and state drug pricing programs, and provides recommendations for expanding existing and developing new programs using models that have been effective. These recommendations include expanding access to the lowest federal price (namely the Federal Ceiling Price); relaxing restrictions on pharmaceutical importation; encouraging state legislation designed to reduce prescription drug costs; encouraging state purchasing pools; regulation of pharmaceutical marketing and advertising costs; encouraging transparency in the market; promoting availability of generic medicines and reforming patent protection.

Please see attached paper entitled "AHF's Recommendations for Domestic Drug Pricing."

RECOMMENDATIONS FOR DOMESTIC DRUG PRICING



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AIDS HEALTHCARE FOUNDATION

Objective of Essay:

In light of the soaring cost of pharmaceutical medicines, in particular the cost of antiretroviral therapy for people living with HIV, this essay examines domestic drug pricing issues and sets forth recommendations for AIDS advocates and policy makers to use in order to effectively work toward greater access to affordable prescription drugs.

Executive Summary:

The soaring cost of prescription drugs is an issue that is at the forefront of American politics and news. Every day there are dozens of stories about people who are unable to afford their prescribed drugs and are forced to choose between things like paying the electric bill and filling a prescription. In federal, state and local governments across the country, legislation and policies have been set forth to combat these rising costs; tackling the issue from many directions, yet never seeming to make much progress. Advocates maintain that the pharmaceutical industry is virtually unregulated and charges inflated prices that Americans have no choice but to pay. The industry answers back that the price of prescription drugs reflects the high cost of researching, developing and producing new products. Whether one identifies with the advocates' or the industry's point of view, it is clear that the current high cost of prescription drugs prevents millions of people from accessing much needed, and often life-saving, medicines.

This paper examines methods that governments, public and private entities, and health care advocates can pursue to establish and access lower priced prescription drugs, especially with respect to antiretroviral drugs (ARVs). The paper

2005 AIDS HEALTHCARE FOUNDATION

provides background on current federal and state drug pricing programs, and provides recommendations for expanding existing and developing new programs using models that have been effective. These recommendations include expanding access to the lowest federal price (namely, the Federal Ceiling Price); encouraging state legislation designed to reduce prescription drug costs and relaxing restrictions on pharmaceutical importation. These recommendations include increasing supplemental rebates and using the state Medicaid program to leverage lower prescription drug prices for other state programs; preferred drug lists and prior authorization; establishing fair drug pricing boards; and encouraging bulk-purchasing through purchasing pools. The final recommendations are aimed at prescription drug reform. These recommendations include controlling marketing and advertising costs; establishing transparency in the market; and promoting greater availability of generic medicines and reforming patent protection laws.

Background:

Health expenditures in the US grew 7.7% in 2003 to $1.7 trillion.[1] The cost of prescription drugs is one of the fastest growing components of health care spending, increasing 10.7% in 2003.[2] In 2002, spending in the US for prescription drugs totaled $162.4 billion, four times greater than the amount spent a decade ago.[3] The pharmaceutical industry was the third most profitable industry in the country, with annual profits (return on revenues) of 14%, compared to the 5% average for other Fortune 500 companies.[4]

Antiretroviral drug therapy used by HIV positive patients costs on average $10,000 to $12,000 per patient per year.[5] This amount does not reflect the recent introduction of drugs into the market like Roche's Fuzeon, which costs over $20,000 annually and Serono Inc.'s growth hormone used to combat AIDS wasting, Serostim, which costs well over $6,000 per month. Considering that 46% of people living with HIV/AIDS have annual incomes of less than $10,000 per year and 63% of HIV positive individuals spend at least part of the year unemployed, the escalating cost of AIDS-related drugs places a large burden on public health care financing.[6] It is estimated that as many as 83% of HIV positive persons who are in care must rely on the public sector. As a result, national drug retail expenditures for antiretrovirals (ARVs) totaled nearly $2.6 billion in 2001.[7]

Because of the increasing cost of prescription drugs and the great demand for the newest and most expensive drugs, advocates and policy makers must consider a combination of drug pricing options, cost containment measures and legislation that can save a significant amount of money. At the same time we must ensure that these drug pricing mechanisms provide the most effective prescription drug coverage to the maximum number of people. In 2005, almost

two-thirds of all Americans say there should be more government regulation on escalating prescription drug prices.[8] In an atmosphere of budget cutbacks and increasing health care costs, AHF recognizes that the ideas for drug pricing reform must be innovative and far-reaching.

This paper will specifically examine domestic drug pricing of AIDS-related drugs and the programs and measures that allow people living with HIV/AIDS to access these expensive, life-saving therapies. In addition, recommendations will be made to help ensure that public financing of AIDS-related care is available for all in need. In light of the fact that HIV/AIDS care is provided by many different programs throughout the public and private sectors, the recommendations put forth are not limited to AIDS medicines and AIDS funding programs, but would most likely be applicable to many other public funded prescription drug programs.

ADJUSTMENTS AND EXPANSIONS IN FEDERAL PROGRAMS:

The federal government purchases the vast majority of prescription drugs for persons living with HIV/AIDS in the US. In 2003, the AIDS Drug Assistance Program (ADAP, Title II of the Ryan White CARE Act), a federal discretionary grant-funded program with annual capped funding, provided treatment for 30% of people living with HIV and AIDS (PLWHA), or over 135,000 people.[9] Federal Medicaid programs paid for the care and treatment of 44% of PLWHA, Medicare paid for 6%, and 13% of PLWHA were dually eligible for both Medicaid and Medicare.[10] Since the federal government is such a large purchaser of prescription drugs for PLWHA, it is reasonable that the first place to start this study is to look at different federal drug purchasers and try to structure programs that emulate systems at this level that are both cost effective and proven.

Under federal law, a number of drug discount programs have been created to ensure that prices paid by federal purchasers generate the deepest discounts. When considering adjustment and expansion efforts aimed at lowering the cost of prescription drugs, there are five federal programs that are particularly important: Medicaid Rebate Program, Federal Supply Schedule (FSS), 340B Program, Federal Ceiling Price (FCP) and VA National Contract Price.

• MEDICAID REBATE PROGRAM

In 2001, Medicaid expenditures on prescription drugs totaled $20 billion.[11] Medicaid is the largest payer of prescription drugs nationally, consuming 14% of the drug market.[12] The Centers for Medicare and Medicaid Services (CMS) project that Medicaid drug expenditures will increase by an average 12.7% annually through 2011.[13] The Medicaid Rebate Program (MRP) was created by the Omnibus Budget Reconciliation Act (OBRA) of 1990, and it requires

drug manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) for states to receive federal funding for outpatient drugs dispensed to Medicaid patients. The drug rebate program was amended by the Veterans Health Care Act of 1992 and now requires manufacturers to also enter into pricing agreements with other programs like the 340B drug pricing program, FSS, FCP and other VA contracts. Drug manufacturers must negotiate and sign an agreement with these programs in order to have their drugs placed on the national Medicaid formulary without prior authorization restrictions. Approximately 550 pharmaceutical companies currently participate in the Medicaid Rebate Program.[14] Forty-nine states (Arizona is excluded) and the District of Columbia cover drugs under the MRP.

The rebate amount is statutorily defined using the average manufacturers price (AMP). The current rebate is the best of either 15.1% of the AMP per unit or the difference between the AMP and the best price per unit. For non-innovator drugs (generics), the rebate is 11% of the AMP per unit. The price of drugs are often compared using the Average Wholesale Price (AWP), a national average of list prices charged by wholesalers to pharmacies, because this price is publicly available. AWP is also referred to as the *sticker price* because it does not properly reflect the actual price that large purchasers normally pay. Recent reports from the Office of Inspector General (OIG) and other researchers have found that AWP substantially overstates pharmacies' actual acquisition costs, discrediting the validity of any cost comparisons. Although this is true, it is still the most accurate and available method used to compare prices from different programs. The Medicaid net rebate price is estimated to be the AWP minus 39.5%.[15]

In addition to the statutorily defined Medicaid rebate, states are also allowed to negotiate a supplemental rebate for Medicaid drugs. According to Kaiser Family Foundation, 26 states have created supplemental rebate programs, at least nine of which rely on Preferred Drug Lists (PDLs) and Prior Authorization (PA) to incentivize manufacturers to negotiate with states.[16] The negotiations are confidential and therefore savings to states are difficult to quantify.

- **FEDERAL SUPPLY SCHEDULE:**

The FSS is a schedule of multiple award contracts and prices used by federal agencies and other specified entities to purchase supplies and services from outside vendors. FSS prices for the pharmaceutical schedule are negotiated by the Veterans Administration (VA) and are based on the prices that manufacturers charge their "most-favored" non-federal customers. FSS prices are publicly available and prices average AWP minus 48.3%.[17] Under section 603

of the Veterans Health Care Act, manufacturers are required to list all their brand name drugs on the FSS as a condition for having their drugs covered and reimbursed by the Medicaid program. This requirement has encouraged virtually every brand name drug company to sell through the FSS and has prevented companies from picking and choosing which drugs to list. On average, FSS prices are estimated to be 15% lower than Medicaid prices.[18]

- **THE 340B PROGRAM:**

The 340B program establishes a maximum price that manufacturers can charge covered entities participating in the Public Health Service's 340B drug discount program. 340B-covered entities include state or local government disproportionate share hospitals (DSHs) and 11 categories of facilities or programs funded by the Health Resource and Services Administration (HRSA). There are over 10,000 340B-covered entities and these clinics, health care centers and hospitals serve more than 10 million people.[19] The AIDS Drug Assistance Program (ADAP) is one of the eleven categories that is funded by HRSA and is allowed to purchase at 340B prices. The 340B price is calculated using the Medicaid rebate formula and is deducted from the manufacturer's selling price, and therefore not paid as a rebate. 340B-covered entities receive a minimum rebate of AMP minus 15.1% for brand-drugs and AMP minus 11% for generic versions of drugs. 340B prices are on average AWP minus 51%.[20]

- **THE FEDERAL CEILING PRICE:**

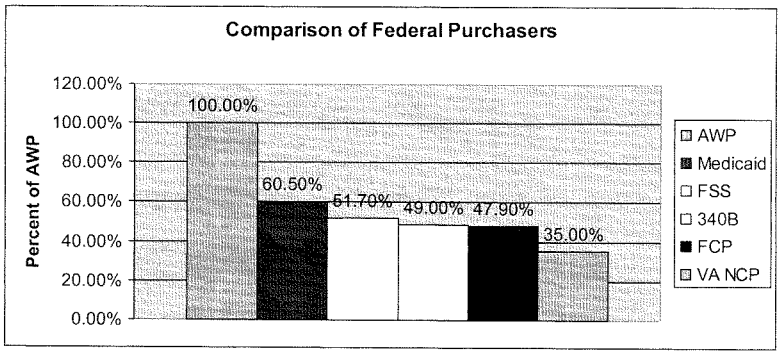
The Federal Ceiling Price (FCP) is a statutorily set discount to which the Big 4 (Veterans Administration, Department of Defense, Public Health Services and Coast Guard) have access. FCP must be at least 24% below the non-federal average manufacturers price (non-FAMP, the average price paid by commercial, non-Federal purchasers), but often the VA, which manages the FCP formulary, is able to negotiate sub-ceiling prices. FCP discounts on Big 4 "covered drugs" extend only to brand name drugs. FCP is estimated to be AWP minus 52.1% and on average is estimated to be 21% lower than the Medicaid net price.[21] Approximately 6,300 products are on the FCP, and for 63% of these products the FCP price was lower than the FSS price, 14% of products had equal FSS and FCP prices, and for 23% of the products the FCP price is slightly higher than the FSS price. [22]

- **VA CONTRACTS:**

Currently, only the VA and the Department of Defense have access to the prices established under the fifth federal program mentioned above, VA national contract prices (NCPs). This is the price the VA has obtained through competitive bids from manufacturers for select drugs in exchange for inclusion on the VA formulary. On average, VA contract prices are as

little as 65% below AWP and are by far the lowest price available to any federal purchaser.[23] VA contract prices are 43% lower, on average, compared to Medicaid net price.[24] The VA is able to negotiate sub-ceiling contract prices for a number of reasons: NCPs are exempt from Medicaid *best price*; NCPs for brand drugs are prohibited by law from exceeding a specified ceiling price; and VA has the authority and tools to negotiate sub-ceiling prices.

In a report comparing the net price (reimbursement price minus rebates) that ten state Medicaid agencies paid for 16 HIV/AIDS ARVs to the prices paid by other government purchasers, specifically FCP, FSS and 340B, it was found that Medicaid pays up to 33% more than other federal government drug discount programs for those drugs. The report also found that on average Medicaid pays 61 cents more per pill, or $66 more per prescription, than these other federal agencies that purchase at FCP or FSS. In addition, Medicaid pays five percent more for ARVs than ADAPs with identical drug distribution structures. [25]



Recommendations:

Recommendation 1 — Expand Access to Lowest Federal Prices: "VA as a Model"

An ideal solution to the problem of skyrocketing prices of AIDS drugs would be to establish that all federal and state programs that purchase AIDS drugs not pay any more for these prescription drugs than the lowest price available to the federal government. Clearly, the most successful federal drug purchaser and the program able to establish the lowest prices is the Veterans Administration. Internally at AHF, this idea has been dubbed the "VA model," inferring that the lowest federal price is the VA price. Although this is most often true, it is possible

for the FSS or 340B price for a drug to be lower than the price available only to the VA. This can occur when the VA, which negotiates set prices for the FSS, or the PVP or 340B covered entities, is able to negotiate sub 340B ceiling prices.

The VA is most often able to secure the lowest prices for a number of reasons. The first is that the ceiling-price from which it starts negotiations (i.e. the FCP) is defined by a statute—24% below non-FAMP. The VA's ability to move market share to preferred vendors also entices manufacturers to contract sub-ceiling prices. The VA manages a common formulary and has good compliance among its doctors and pharmacists. This allows the VA to commit up front to a significant volume of drugs. These are all factors that make the VA a successful purchaser.

In a January 2004 analysis of AHF's California state Assembly Bill 881, it was estimated that MediCal (California's Medicaid program) would save $108 million if drug manufacturers gave MediCal the same net price that manufacturers give to the Big 4 (which purchase at FCP) and $680 million if allowed to purchase at VA national contract prices.[30] Clearly, the savings potential for all states and for the federal government is great, but other issues must first be considered.

From a state perspective, sub-ceiling negotiation is only possible if the mandatory discount is established by statute or regulation. If the discount is arrived at through contract negotiation, it is hard to imagine any manufacturer entering a contract that provides for a second round of negotiations. But mandating a price ceiling as such may have other implications. Some industry insiders have theorized that if ceiling prices on prescription drugs were mandated, manufacturers may threaten to pull out of the system, actually leading to decreased access to necessary drugs in the marketplace.

Despite this speculation there is precedence for states pursuing legislation to establish a ceiling price similar or equal to the lowest federal drug prices: Arizona, Illinois, Pennsylvania, and Vermont, are among the states that have pursued legislation to allow purchasers such as Medicaid to purchase at lower federal prices including the FSS and FCP.[31] None of these proposed bills have yet been passed. In 2000, Maine passed a controversial state prescription assistance program that sets the suggested ceiling price to start negotiations that was equal to that of the FSS. Although the legislation passed, the legality of the program has been questioned. The Maine Rx program is discussed in more detail later in this paper.

What is the feasibility of passing legislation that would ensure that federal and state purchasers do not pay more than the lowest federal price? There is likely to be great resistance

from pharmaceutical manufacturers, as Medicaid represents approximately 14% of the domestic market share, while the federal purchasers such as FSS, VA and 340B each consume only 1%.[32, 33] Any such proposal is also likely to bring about legal challenges that may argue that the legislation violates commerce or supremacy clauses of the US Constitution.[34,35] Manufacturers may also be resistant because they face liability for fraud for each statutory program, including submission of false or misleading data upon which federal reimbursement is based.[36] Risk is particularly significant with respect to Medicaid rebate issues: dollars are significant and therefore visible and whistleblowers are attentive to the issue. Also, in light of the changes that will occur in January 2006 with the full implementation of the federal Medicare Modernization Act (MMA), states are concerned that they may lose a significant portion of their bargaining power, when all of the dually eligible clients are switched over to Medicare as the primary payer for medications.

In recent years, ADAPs have witnessed unprecedented growth in program enrollment, utilization, and expenditures. The high cost of combination therapy has placed pressure on ADAPs to adopt a wide variety of cost-containment and price control strategies to maximize resources. One possible solution to this problem is to set the ceiling price for ADAPs at the lowest price that the federal government pays. This proposal is similar to the one above, except the concept of using ADAP in a *demonstration project* capacity would be to prove that purchasing groups other than the Big 4 can successfully access the lowest federal price without compromising the integrity of the other federal programs. Since ADAPs comprise such a small percentage of the public prescription drug market as compared to a program like Medicaid, this demonstration project may be viewed as less risky and threatening, and therefore face less resistance from the industry. Essentially, the demonstration project could be used to prove that FCP and VA prices can be expanded beyond the small group that currently has access to it.

Expanding the lowest federal prices to other smaller purchasers like ADAP is beneficial for a couple of reasons. There will likely be less resistance from manufacturers and others as ADAP makes up a miniscule percentage of the domestic drug market, less than one percent. Since 340B purchases are excluded from the Medicaid Best Price rule, ADAPs purchasing at the lowest federal price will not impact other federal purchasers. Also, there is research that indicates that, if ADAPs were allowed to access federal prices, the programs could save millions of dollars. According to a 2000 Office of Inspector General report, ADAP prices are 16% higher than FCP. According to OIG, state ADAPs collectively could have saved nearly $58 million in 1999 if allowed to purchase just 10 AIDS drugs at FCP.[37]

It is also easier to make the connection between ADAP and FCP, than it is between Medicaid and FCP. The 340B program (through which ADAPs are allowed to purchase) was created out of Section 602 of the Veteran's Healthcare Act of 1992, the same act that enacted the FSS and FCP federal pricing schemes. There is no language in the legislation establishing FCP that prohibits other entities from purchasing at these lower prices or from negotiating.[38] It is important to consider the potential benefits for manufacturers if state ADAPs are allowed to purchase at the lowest federal price, including a simplified, uniform federal pricing system to track and report, with price-changing data submissions and recalculations required only once a year.

The potential problems with this legislation are significant. When opening up FSS, FCP and VA prices to other purchasers, consideration should be given to how it will affect the prices of the other federal and private programs. There are also legal issues to consider. One must be aware of how ADAP, FSS, FCP and VA formularies compare. If many of the drugs on the ADAP formulary are not also on the federal formularies, such legislation will not be effective.

Recommendation 2 — Relax Restrictions on Importation of Pharmaceuticals

The issue of importation has been hotly contested in the US for the past several years. The controversy as it is generally played out pits 'cost-conscious' consumers against 'greedy' pharmaceutical giants, and somewhere in between are the policy makers and legislators who are trying to decipher the truth. Advocates of importation argue that the possible savings are great. It is estimated that retail prices in Canada are 30% to 72% lower than in the US.[39] Advocates also attest that the drugs are safe, since the standards of the pharmaceutical regulatory boards of other countries, like Canada are similar to that of the US' Food and Drug Administration (FDA). Opponents argue that safety and efficacy of the drugs imported from other countries cannot be closely monitored and therefore importing drugs from any other country poses many possible dangers.

Federal law currently prohibits the importation and re-importation of pharmaceutical drugs from other countries. Importation occurs when a drug is manufactured in another country where the prices of drugs are lower, usually as a result of price controls. An individual or group purchases these cheaper drugs from a company in another country and the drugs are shipped to the US for use. Re-importation occurs when pills are manufactured in the US, sent to another country for sale through a foreign pharmacy, and eventually shipped back to the US for sale at a lower price than is available through American pharmacies.[40] Although these terms technically refer to two different methods of acquiring drugs, the words are often used

interchangeably. For the purposes of this paper the term importation will be used to refer to both.

Although, importing drugs is prohibited, the FDA does not recommend a penalty for people who violate the law as long as it is for personal use. In fact, according to a recent survey, in 2003 7% of Americans purchased some prescription drugs from Canada.[41] A Kaiser Family Foundation (KFF) report suggests that 80% of people over age 50 support importation and 68% of Americans favor further legislation that would make it legal.[42] Over the past couple of years, Congress has repeatedly enacted laws that loosen the restrictions on importation from some countries, but each time it has included a caveat that the HHS Secretary must certify the safety and cost savings before giving the legislation the final okay. The past two HHS Secretaries, Donna Shalala during the Clinton Administration and Tommy Thompson during the Bush Administration, have failed to give this final approval, stating that the safety of imported drugs cannot be guaranteed.

In spite of this, advocates continue to point to the benefits of importation, namely that cost savings greatly outweigh the minimal safety concerns involved. The Congressional Budget Office (CBO) projects potential savings to the federal budget of $4.5 billion over the next ten years and total savings (public and private) of up to $40 billion over the next ten years.[43] Since the HHS Secretaries have not given final approval, and therefore the federal government has yet to ascertain any effectual changes in the law, a number of states have taken it upon themselves to establish legislation that allows and encourages importation of prescription drugs, namely from Canada. Minnesota and Massachusetts in particular have taken strides to establish legal importation of drugs. Minnesota has established a website that residents can visit to get more information on importation and contact information for Canadian pharmacies. The city of Springfield, Massachusetts has enacted legislation allowing people to fax prescriptions to pharmacies in Canada and receive the drugs via mail.

AHF has always concerned itself with the safety and efficacy of treatment for people living with HIV and AIDS. With over 18 years of experience providing specialized medicine to HIV positive individuals, its first and foremost concern is for the well being of its patients. Beyond this, the organization also recognizes the need for affordable heath care, in particular reasonably priced prescription drugs. It is AHF's position that importation is a cost-effective, stop-gap measure that will allow more people to access life-saving medicines. Restrictions surrounding importation should be relaxed and a proper system should be set up that will help guarantee the safety of imported drugs.

State Actions to Reduce Prescription Drug Costs:

States are employing a wide range of methods in an attempt to rein in high prescription drug costs. In most states, the provision of health care benefits to the uninsured and underinsured is a significant part of the budget, usually falling second only to primary and secondary education. Often spending upward of 30% of state funds on health care, states are looking for inventive and permanent ways to save money. Prescription drug prices have become one of the primary targets for legislators to attempt to control these costs. But legislation dealing with these costs is often an uphill battle, with pharmaceutical manufacturers mounting counter offenses to thwart many proposals that reach legislatures.

Recommendation 3 — Encourage State Legislation Designed to Reduce Prescription Drug Costs

Maine RX was enacted by the state legislature in 2000, with the intention of providing access to affordable prescription drugs for 325,000 Maine residents who lacked insurance. The law has a number of different facets to be phased in over time, the first of which is a mandatory 10% discount that manufacturers were required to offer on all drugs. Included in the law is a profiting prohibition clause that penalizes manufacturers, distributors and labelers of prescription drugs if they charge "unconscionable prices or restrict sale of drugs to the state." The penalties are levied in the form of injunctions and monetary damages. A third caveat of the law mandated that in 2003 the state would establish maximum retail prices for every drug. Participation in the program was mandatory for manufacturers. If any refuse to participate, it results at the company's drugs being placed on prior authorization on the Medicaid formulary, often this is referred to as using Medicaid as leverage.

The threat of prior authorization for pharmaceuticals is a commonly disputed issue. Putting a drug on prior authorization is intended to discourage doctors from prescribing that particular brand. The paperwork and administrative effort involved in accessing drugs on prior authorization are extensive. Also, states use prior authorization as a way to educate providers about other, more cost-effective drugs; in many cases prior authorization requires that the prescribing provider speak directly with a pharmacist who is instructed to provide information on alternative treatments. Often a provider views this as an annoyance and avoids prescribing the drug altogether. As a result, drug companies will try to avoid the sanction of having their products placed on prior authorization because restricted access to the Medicaid population is too great a loss.

Is this a fair bargaining tool? Some advocates argue that using the buying power of state Medicaid programs is the best negotiating tool that exists to compel manufacturers to set competitive prices. Others argue that leveraging the Medicaid population is unethical and increases the burden on an already at-risk population. Opponents further argue that if a drug is placed on prior authorization for Medicaid because a manufacturer refuses to negotiate a lower price for the drug for a different state program, it is the Medicaid population that suffers. Proponents answer back that the threat to the Medicaid population is minimal and, in theory, Medicaid patients are able to access a therapeutic equivalent to the brand that has been placed on prior authorization. Therefore proponents contend that using the Medicaid hammer should not jeopardize the continuity of care for Medicaid patients.

It is AHF's position that leveraging the negotiating power of Medicaid is an effective method for states to compel drug companies to provide cheaper prices for drugs for other public programs. HIV is a very complicated disease that involves complex regimens using multiple drugs. It is common for HIV patients to only respond to one or two specific combinations of medications and, if one of these drugs is on prior authorization, it could lead to a problem and pose a danger to the health of the patient. That said, AHF recognizes that the state and public health providers must have leverage to effectively negotiate with manufacturers to establish appropriate prices. If this tool were taken away from states, AHF believes it would ultimately lead to less access because the state would be unable to establish fair prices on drugs for other public programs. Furthermore, it is a leap to say that manufacturers will not deal with states and will allow its drugs to be placed on prior authorization for Medicaid. The threat of losing access to this large buying group is too great and manufacturers are always looking out for the bottom line.

There are many other legislative actions that different states have taken to stem the increasing cost of prescription drugs: establishing prescription drug fair-pricing boards that attempt to establish a reasonable price for products; ordering drug cost studies that try to ascertain what states are actually paying; limiting manufacturer's marketing and advertising costs; and encouraging bulk-purchasing. All these mechanisms deserve further study to help determine "best practices" for reducing drug prices.

Recommendation 4 — Encourage State Purchasing Pools

The idea of group or pool purchasing is not new in a commercial market. The underlying theory that greater purchase volume yields greater negotiating power is key. Purchasing pools are common at the federal level. One example is the partnership between the Veteran's Ad-

ministration and the Department of Defense, which share common formularies and purchasers and therefore both benefit from greater negotiating power.

The same model is currently being used at the state level: legislation establishing interstate and intrastate purchasing pools is becoming more common. In 2000, the state of Massachusetts created a program to combine various state purchasers, including senior prescription assistance programs, Medicaid enrollees, state workers and programs for the uninsured and underinsured, into a single purchaser. As of February 2005, there are three operating multi-state bulk buying pools, not counting several additional variations and many single state initiatives.

The three multi-state bulk buying pools are the National Medicaid Pooling Initiative (NMPI) in which eight states participate; the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), which combines agencies in 41 states; and RXIS, a program established by West Virginia and joined by Delaware, Missouri, New Mexico and Ohio, that pools the drug purchasing programs for state employees and other state programs (excluding Medicaid) into one large purchaser. In RXIS the states use common preferred drug lists and rebate negotiations to access lower prices. Over three years, West Virginia alone estimated that this purchasing pool saved the state $25 million, or 5% of its costs on prescription drugs. [44]

AHF's position is that the use of state purchasing pools and bulk-purchasing are effective ways to wield negotiating power. While it is not the final answer to the high costs that states pay for prescription drugs, it is a proactive step that will yield increased access to prescription drugs for more people.

Prescription Drug Reform:

A recent survey that examined adult Americans' perception of the pharmaceutical industry revealed what many have known intuitively for a long time, people generally distrust and have an unfavorable opinion of "big pharma." One-half of all adults surveyed have an unfavorable opinion of the pharmaceutical industry, with drug companies falling just behind the oil and tobacco industries in approval ratings and consumer confidence. Furthermore, seven in ten adults say that the high profits made by drug companies is one of the strongest driving factors in the increasing cost of health care.[45]

Although the recommendations above are important measures to stem the increasing cost of prescription drugs, real reform must be made within and to the pharmaceutical industry in order for prices to be contained.

Recommendation 5 — Controlling marketing and advertising costs

It is impossible to turn on the television, flip through a magazine or listen to the radio without hearing an advertisement for the newest wonder drug. Direct-to-consumer advertising (DTCA) for prescription drugs has become such a part of American culture that one hardly notices the constant barrage to "ask you doctor" or "call to find out more." In 2003, manufacturers spent $25.3 billion On advertising, with $21 billion of that directed at physicians through free drug samples, gifts and other perks.[46] In spite of this, only 18% of adults say that they trust what drug manufacturers say in their ads.[47]

Manufacturers often espouse the position that the high costs of prescription drugs is attributable to the risk and expense involved in research and development (R & D) of new drugs. Although pharmaceutical manufacturers have been using this argument for a long time, recent surveys suggest that the public just isn't buying it. Seventy-four percent of people surveyed do not believe that R & D costs are a major driving force in the increasing price of drugs; instead they believe that profit margins and marketing costs are the largest contributors to high prices.[48]

A 2002 report by Familiy Health International of nine top brand pharmaceutical manufacturers found on average that manufacturers spent 27% of revenue on the marketing and advertising of drugs and only 11% on R & D.[49] A 2001 report found that brand name drug makers in the US employ 81% more people to market their drugs than to research and develop drugs.[50] And from 1995 to 2000 marketing staff of the nine big manufacturers increased by 59% while research staff decreased by 2%.[51]

With 81% of consumers believing that drug costs are unjustified, something must be done to reel in prices.[52] AHF's position is that one of the major driving forces of increasing drug costs is the amount of money manufacturers put into marketing and advertising. This expense is eventually passed on to consumers. In California, AHF has introduced Assembly Bill 95 (Koretz, D-West Hollywood) to address this issue.[53] The bill requires manufacturers to disclose how much money they spend on marketing and advertising drugs for chronic diseases and to pay a percentage of this amount as a rebate to the state. This legislation makes a policy statement that says California will no longer pay for these enormous marketing costs.

AHF has also sent out an "AIDS Education Pledge" to all the major manufacturers of AIDS drugs. The pledge asks manufacturers to sign on and guarantee that when marketing HIV/AIDS drugs they will only use "help-seeking" advertisements (also called unbranded outreach), which educate consumers about their disease. AHF believes that this is especially im-

portant for the PLWHA population because prescribing decisions are complex and should be made by HIV-certified physicians and should not be influenced by high-priced ad campaigns.

Recommendation 6 — Establish Transparency in the Market

Many economists will tell you that a key component of an efficient commercial market is the availability of complete and accurate information on a product's quality and price. Access to such information is crucial for a competitive market to exist. In contrast to this principle, the pharmaceutical industry is shrouded by proprietary constraints, an issue that has led to a lot of debate and discussion. The main issue that is debated is whether or not a transparent market ultimately leads to better prices for consumers.

The industry argues that the confidentiality of prices, contracts, rebate amounts, etc. is necessary in order for manufacturers to negotiate effectively with all the different public and private purchasers. Advocates, on the other hand, argue that the lack of transparency is yet another way that the industry has been able to deceive consumers, because, as the system currently exists, the absence of pricing information limits the ability of purchasers to ensure that they are getting the best possible price.

Proponents of establishing transparency within the pharmaceutical market argue that the information gained would improve economic efficiency in the market, empower buyers to negotiate more effectively, give policy makers and researchers access to prices, and make the pharmaceutical industry accountable to consumers. Transparency in the market would be particularly beneficial to cash paying customers because, in theory, transparency would open up the market for competition and eventually set the price at a reasonable level, likely a lower price. The industry contends that keeping information—such as pricing—proprietary allows manufacturers to negotiate good deals with the best customers. This argument is obviously important to public programs who are the "best customers" and rely on getting rates that are less than the private market.

AHF's position is that an efficient commercial market is crucial to the establishment of fair prices for prescription drugs. If the market were open and transparent, competition would rule. Once real competition exists, manufacturers will have to set prices at a fair level or will lose out to their competitors.

Recommendation 7 — Promote Availability of Generic Medicines and Reform Patent Protection

A pharmaceutical drug patent lasts for 20 years, during which time the innovator company (brand name manufacturer) is given the sole right to market and sell the product. When the patent period expires, generic manufacturers can apply to the FDA to sell generic versions of the drug. A generic drug is identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

Generic drugs cost less than half the price of their brand name counterparts and the availability of these drugs in the market often drives down the price of branded drugs.[54] According to the CBO, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies.[55] Although the savings are great, US generic sales totaled $11.1 billion in 2001 compared with $121 billion for branded drugs.[56]

Promoting the use of generics is a significant cost-savings tool. Patients using generic drugs receive medicine that is equivalent to the branded counterpart, but costs half as much. Availability of generic alternatives to expensive branded drugs allows increased access to high quality and effective prescription drugs in the US. The question remains, what is the best way to promote the use of generics? Educating the public on the safety, efficacy and cost savings associated with generic drugs is crucial to support these efforts. In addition, federal, state and local governments, employers, public and private providers and opinion leaders can all play a part in promoting the use of generic medicines.

PBMs can promote the use of generics through their formularies, pricing contracts with pharmacies, and higher co-pays for branded drugs. Unfortunately, over the last decade many of the largest PBMs have been acquired by large pharmaceutical manufacturers; PCS was bought by Eli Lilly in 1994 for $4 billion; Medco (both a PBM and a mail-order pharmacy) was acquired by Merck in 1993 for $6.6 billion; and Diversified Pharmaceutical Services was purchased by SmithKline Beecham (now GlaxoSmithKline) in 1994 for $2.3 billion.[57] Such a relationship establishes an intrinsic conflict in which PBMs are incentivized to sell branded drugs, the results of which are higher priced drugs passed on to the consumer.

It is impossible to separate the issue of generic drugs from the issue of pharmaceutical patent protection. There has long been a dispute over the 20-year patent protection period for manufacturers. The industry argues that since a patent is granted very early in the development process, the market exclusivity period is actually less than 20 years. Advocates attest

that 20 years is too long to give exclusivity to one manufacturer and that patents prevent competition in the marketplace, establishing inflated prices.

Since all ARVs are still under patent, generic drug use among the HIV/AIDS population has not been an issue. AZT (zidovudine), the first anti-AIDS drug approved in the US, is set to expire in June 2005. Issues around the use of generics in the PLWHA population will likely increase over the next decade when first-line ARVs come off patent protection. In addition, as the education around the use of generic medicines increases and as federal AIDS funding continues to fall short, AIDS advocates are likely to recognize the need to get these cheaper drugs on the market more quickly. This will lead to much needed debate over pharmaceutical patent protection, market exclusivity rights, proper incentives for R & D and the need for more regulation of and transparency in the pharmaceutical industry with respect to bringing new drugs to the market.

Conclusion:

Pharmaceutical prices are high and getting higher. CMS projects that prescription drug spending will increase by more than 150% by 2013 to $520 billion a year.[58] This is a cost that families cannot manage, employers cannot bear and the government cannot afford. If nothing is done to rein in the escalating cost of prescription drugs, millions of people will be forced to either forego life-saving drugs or impoverish themselves trying to pay for them. This issue is particularly important to people living with HIV/AIDS who rely completely on consistent access to antiretroviral medications. The recommendations laid out above are intended to establish fair pricing for prescription drugs, pricing that guarantees access to all who need it and maintains sufficient financial incentives for manufacturers to continue to take the risks involved in researching and developing new therapies. Currently, this balance does not exist. However, through continued advocacy and policy efforts on the federal, state and local levels, an appropriate market value for these indispensable and often life-saving prescription drugs will be established.

Established in 1987, AIDS Healthcare Foundation (AHF) is the largest specialized provider of HIV/AIDS medical care in the United States and the nation's largest AIDS organization. AHF currently services over 17,000 patients in the US at fourteen outpatient clinics and one inpatient facility located in California and Florida. The mission of the organization is to provide "cutting edge medicine and advocacy regardless of ability to pay." AHF operates California's largest HIV testing program and has developed innovative HIV prevention and testing models. In Florida, AHF operates a Medicaid disease management program in all 67 counties, which serves more than 10,000 Floridians living with HIV/AIDS and has resulted in a savings of $21M to the state. Under its AHF Global Immunity program, AHF also operates sixteen free AIDS treatment clinics providing life-saving care and antiretroviral therapy in Africa, Central America, Asia and Eastern Europe.

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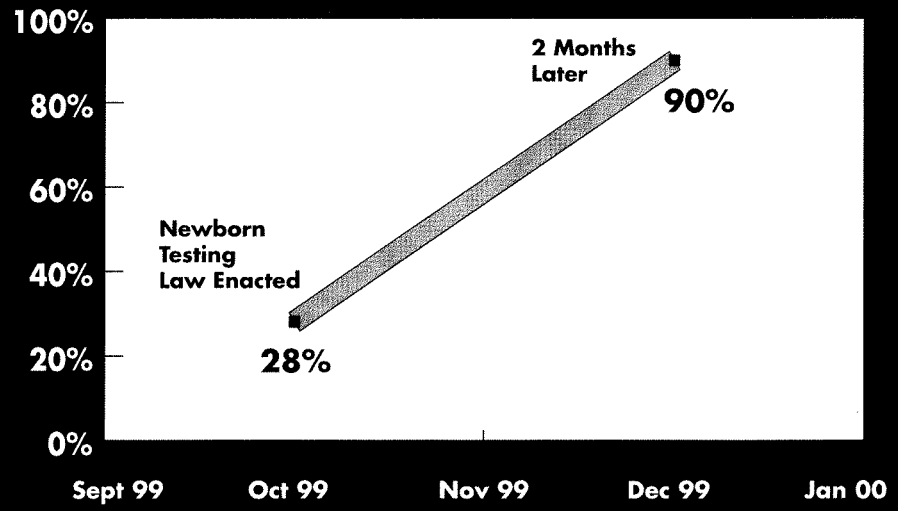
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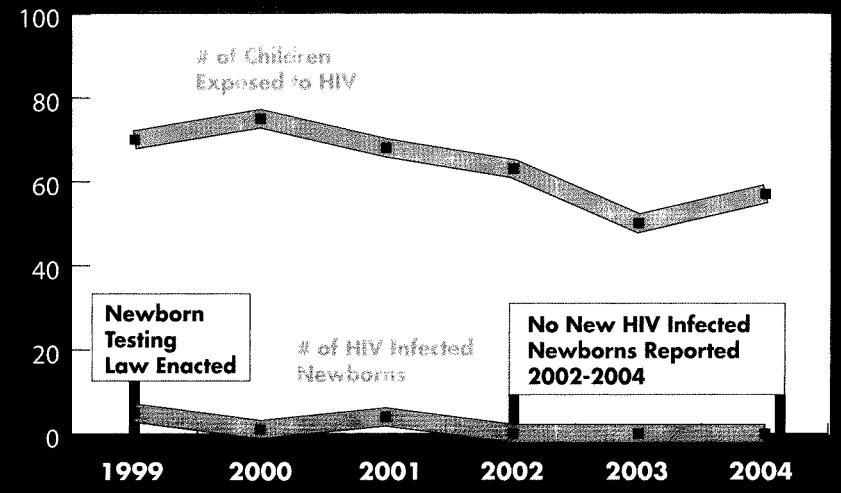
Women Aware of HIV Status Before Delivery: State of Connecticut



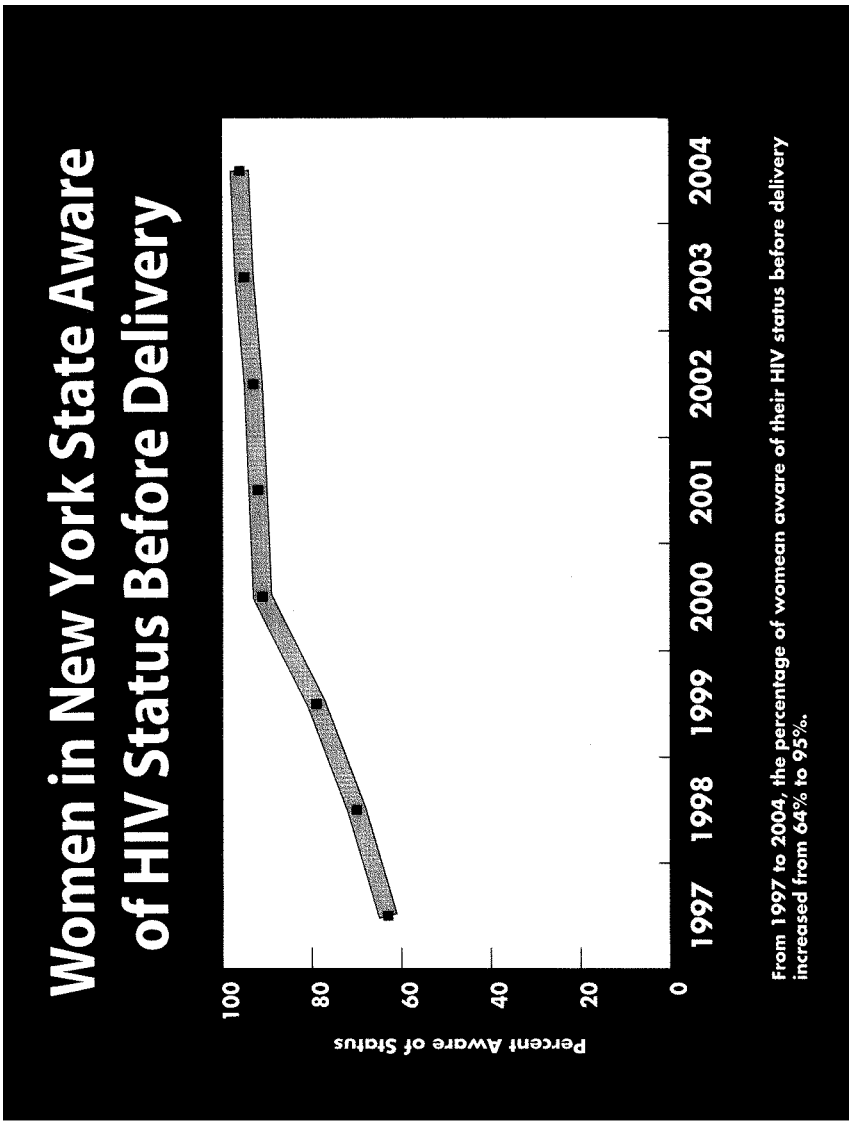
Prenatal HIV Testing Rates BEFORE and AFTER Enactment of Newborn Testing Law
- State of CT Dept. of Public Health

Identifying HIV in Newborn Babies State of Connecticut

HIV-Exposed Newborns and HIV-Infected Newborns 1999-2004



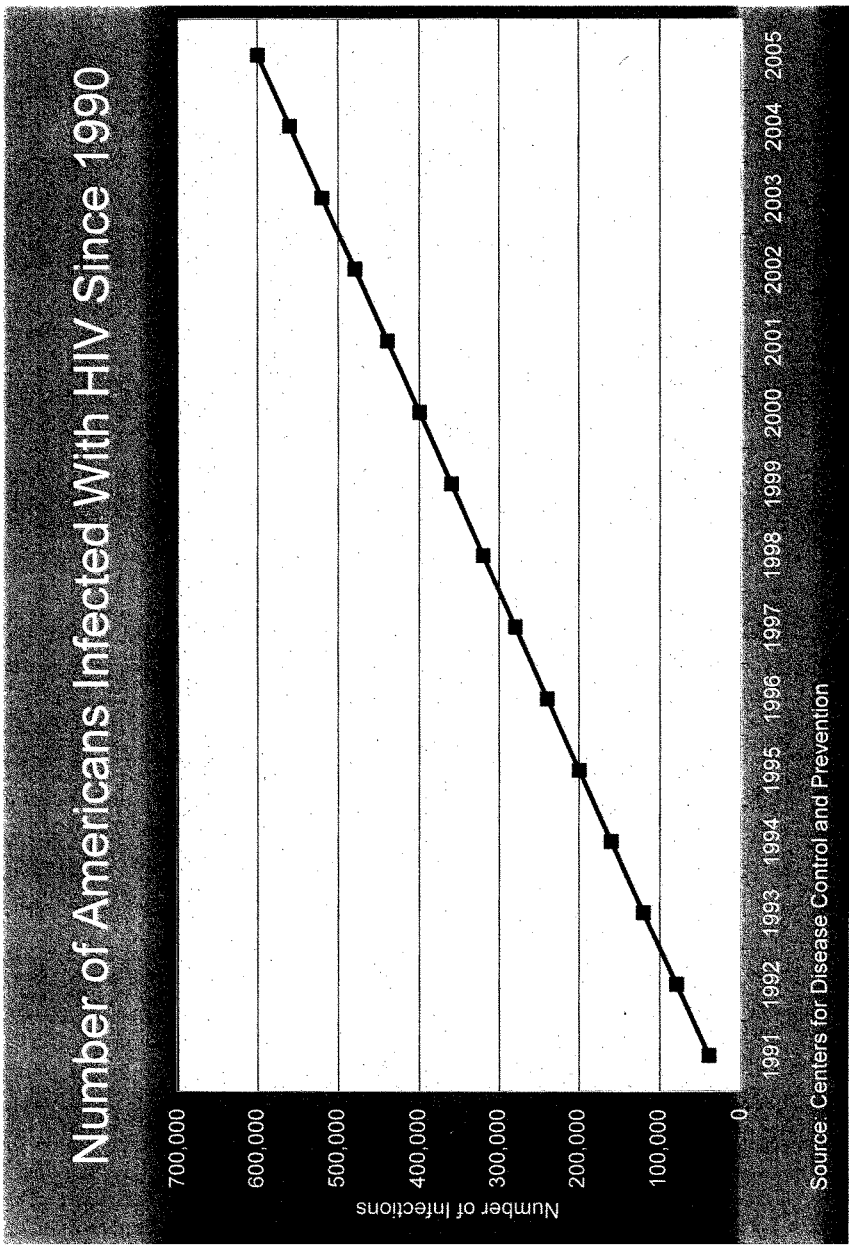
Numbers of Babies with HIV BEFORE & AFTER Enactment of Newborn Testing Law - State of CT Dept. of Public Health


Women in New York State Aware of HIV Status Before Delivery
Percent Aware of Status
0
20
40
60
80
100
1997
1998
1999
2000
2001
2002
2003
2004
From 1997 to 2004, the percentage of womean aware of their HIV status before delivery increased from 64% to 95%.

Cost-Effectiveness of HIV Prevention Intervention

Intervention	People Reached	Annual Cost of Intervention	Infections Prevented	Cost Per Infection Prevented
Notifying sexual partners	54,000	$13,500,000	2,230	$6,100
Community outreach	600,000	$109,096,000	8,921	$12,000
Mass media campaigns	70,000,000	$19,999,000	1,131	$18,000
Increasing condom availability/accessibility	24,905,725	$90,566,000	1,920	$47,000
HIV counseling with "opt in" testing (one-on-one)	1,000,000	$74,000,000	700	$110,000

Cohen DA, Wu S-Y, and Farley TA, "Cost-Effective Allocation of Government Funds to Prevent HIV Infection," Health Affairs, Vol. 24, No. 4, July/August 2005, pp. 915–926.


Number of Americans Infected With HIV Since 1990
Number of Infections
700,000
600,000
500,000
400,000
300,000
200,000
100,000
0
1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005
Source: Centers for Disease Control and Prevention

CDC's Failure to Enforce Federal HIV Spousal Notification Law

In 1996, Congress passed and President Bill Clinton signed a law directing states—as a condition of receiving federal AIDS treatment funds—to enact laws requiring that current and former spouses of HIV infected patients be confidentially notified that they may be at risk for HIV and offered testing and counseling.

Over the past decade, numerous reviews—by the House of Representatives Energy and Commerce Committee, the Health and Human Services Office of Inspector General, the Government Accountability Office and the Senate Subcommittee on Federal Financial Management—have all identified evidence of a lack of proper enforcement of this law.

The Centers for Disease Control and Prevention (CDC), responsible for certifying states' compliance with the law, has dismissed these findings and claims that the law has been and is currently being implemented.

This section contains correspondence and findings regarding enactment of this law.

Concurrent HIV/AIDS diagnosis increases the risk of HIV-related death among persons newly diagnosed with AIDS in New York City, 2002-2004

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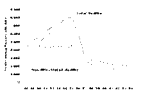
BACKGROUND

Mortality among persons with AIDS in New York City (NYC) peaked in 1994 at 8,040 deaths. Although the number of deaths has declined dramatically due to highly active antiretroviral therapy (HAART), almost 1,500 HIV-related deaths still occur annually in NYC.

Over 25% of persons newly diagnosed with HIV in NYC are concurrently diagnosed with AIDS. Late diagnosis represents missed opportunities for timely initiation of care and treatment.

We assessed the contribution of concurrent HIV/AIDS diagnosis to HIV-related mortality among adults newly diagnosed with AIDS (PWA) in NYC between 2002 and 2004.

Deaths among persons with AIDS in NYC, 1988-2004



Although mortality has declined steeply since 1995, almost 1,500 HIV-related deaths still occur annually.

METHODS

Population

NYC residents 13+ years old diagnosed with AIDS between 2002-2004 and reported to the NYC DOHMH population-based HIV/AIDS registry as of September 30, 2005.

Data sources and collection

Demographic, clinical and HIV transmission factor data were obtained by medical record review and electronic reports of CD4 and HIV RNA viral load tests. Concurrent HIV/AIDS diagnosis was defined as an AIDS diagnosis within 31 days of an HIV diagnosis. AIDS was defined as CD4 count <200 cells/μL or <14% of total lymphocytes or a CDC-defined opportunistic illness (OI).

Vital status and underlying cause of death were determined as of 6/30/05 by matching the HIV/AIDS registry with the NYC Vital Statistics Registry. HIV-related death was defined as ICD-10 codes B20-B24 or for CDC-defined OIs.

Analysis

PWA were followed from date of AIDS diagnosis until death from an HIV-related cause or were censored at death from a non-HIV-related cause or 6/30/05.

Kaplan-Meier survival analysis and the log-rank test were used to test univariate associations with HIV-related mortality. Cox proportional hazards regression was used to determine predictors of HIV-related death in a multivariate analysis.

Subgroup analyses were performed by CD4 count to assess the effect of concurrent HIV/AIDS diagnosis on HIV-related death by level of immune suppression.

RESULTS

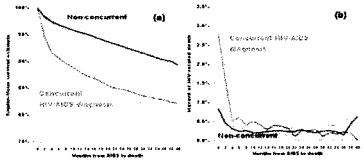
1. Demographic and clinical characteristics of adults newly diagnosed with AIDS in NYC, 2002-2004 (N=13,396)

	%
Median age (years)	41
Sex	
Male	67.2
Female	32.8
Race/ethnicity	
Black	51.6
Hispanic	30.9
White	15.3
API/Native Am./Other	2.3
Borough of residence	
Manhattan	28.9
Brooklyn	29.1
Bronx	24.9
Queens	14.3
Staten Island	1.8
Poverty level*	
Poorer	61.8
Wealthier	33.8
Unknown	4.4
HIV transmission category	
Men who have sex with men	23.1
History of injection drug use	17.2
High-risk heterosexual sex	19.5
Perinatal	0.4
Other/Unknown	39.8
Concurrent HIV/AIDS diagnosis	24.6
Year of AIDS diagnosis	
2002	32.4
2003	37.0
2004	30.6
CD4 count at AIDS diagnosis	
<50 cells/μL	25.3
50-99 cells/μL	12.8
100-199 cells/μL	17.9
200+ cells/μL	14.1
Missing	10.0

*Poverty level was an aggregate measure, based on percent living in zip code of residence below the federal poverty line.

Poorer = at least 20% living below poverty line.

2. Kaplan-Meier survival estimate (a) and hazard of HIV-related death (b), by concurrent HIV/AIDS status



- Of the 1,571 deaths to PWA during the follow-up period, 1,202 (76.5%) were HIV-related.
- 13.8% of HIV-related deaths during this period are attributable to a concurrent HIV/AIDS diagnosis.
- After a median of 23 months of follow-up, 12.7% of PWA died of HIV-related causes. 17.7% of persons with concurrent HIV/AIDS and 11.2% of persons with non-concurrent diagnoses died of HIV [p<0.0001] (2a).
- 50.2% of HIV-related deaths among concurrent HIV/AIDS cases occurred in the first four months, compared to 25.6% among non-concurrent cases (2b).

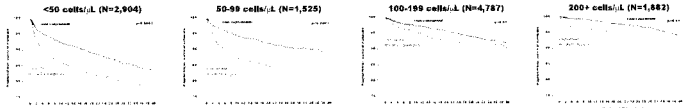
3. Predictors of HIV-related death

	Unadjusted HR (95% CI)	Adjusted HR (95% CI)
Age (ref. = 40 to 49 years)		
13 to 29 years	0.43 (0.33, 0.56)*	0.49 (0.37, 0.65)*
30 to 39 years	0.73 (0.63, 0.85)*	0.79 (0.68, 0.91)*
50 to 59 years	1.45 (1.25, 1.68)*	1.39 (1.20, 1.62)*
60+ years	2.20 (1.80, 2.68)*	2.12 (1.73, 2.59)*
Borough of residence (ref. = Manhattan)		
Brooklyn	1.48 (1.27, 1.71)*	1.22 (1.05, 1.42)*
Bronx	1.32 (1.13, 1.55)*	1.14 (0.97, 1.35)
Queens	0.86 (0.71, 1.08)	0.85 (0.71, 1.10)
Staten Island	1.36 (0.91, 2.05)	1.28 (0.85, 1.93)
Poverty level (ref. = wealthier)		
Poorer	1.42 (1.24, 1.61)*	1.17 (1.01, 1.35)*
Unknown	1.26 (0.94, 1.68)	1.27 (0.91, 1.62)
HIV transmission category (ref. = men who have sex with men)		
History of injection drug use	2.42 (1.97, 2.97)*	1.39 (1.60, 2.48)*
High-risk heterosexual sex	1.43 (1.15, 1.79)*	1.16 (0.91, 1.47)
Perinatal	0.64 (0.16, 2.57)	1.14 (0.28, 4.73)
Other/Unknown	2.61 (2.19, 3.13)*	1.85 (1.52, 2.25)*
Concurrent HIV/AIDS diagnosis (ref. = non-concurrent)	2.17 (1.93, 2.43)*	1.62 (1.44, 1.83)*
Year of AIDS diagnosis (ref. = 2002)		
2003	0.76 (0.66, 0.86)*	0.79 (0.69, 0.90)*
2004	0.70 (0.60, 0.82)*	0.80 (0.68, 0.94)*
CD4 count at AIDS diagnosis (ref. = 100-199 cells/μL)		
<50 cells/μL	2.70 (2.33, 3.12)*	2.27 (1.95, 2.64)*
50-99 cells/μL	1.98 (1.68, 2.39)*	1.74 (1.44, 2.09)*
200+ cells/μL	0.83 (0.68, 0.93)*	0.85 (0.69, 0.95)*
Missing	2.12 (1.82, 2.80)*	1.88 (1.55, 2.28)*

*p<0.05, based on Cox proportional hazards regression model.
Also adjusted for race and race/ethnicity. Abbreviated refer.

Concurrent HIV/AIDS diagnosis was associated with a 62% increase in the risk of HIV-related death. Other significant predictors were increasing age, Brooklyn residence, poverty, history of injection drug use, less recent AIDS diagnosis, and decreasing CD4 count.

4. Effect of concurrent HIV/AIDS status on HIV-related mortality at different levels of immune suppression (CD4 count)



Concurrent HIV/AIDS diagnosis conferred an increased risk of HIV-related death regardless of CD4 count at AIDS diagnosis.

CONCLUSIONS

- Concurrent HIV/AIDS diagnosis is associated with an increase in HIV-related mortality especially within the first four months of diagnosis, and the increase is significant at all levels of immune suppression.
- A small but significant proportion (14%) of HIV-related mortality among persons with AIDS can be attributed to concurrent HIV/AIDS diagnosis.
- Initiatives that promote early diagnosis of HIV infection can reduce HIV-related mortality by giving persons newly diagnosed with HIV the opportunity to begin treatment with HAART before they are immunodepleted.

LIMITATIONS

- Classification of cause of death was not validated by medical record review.
- Deaths occurring outside NYC were not ascertained.
- Regression model did not include AIDS-defining OIs or laboratory values for HIV RNA viral load at time of AIDS diagnosis or before death.

ACKNOWLEDGMENTS

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MAJOR ARTICLES

The Survival Benefits of AIDS Treatment in the United States

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(See the editorial commentary by Vermund, on pages 1–5.)

Background. As widespread adoption of potent combination antiretroviral therapy (ART) reaches its tenth year, our objective was to quantify the cumulative survival benefits of acquired immunodeficiency syndrome (AIDS) care in the United States.

Methods. We defined eras corresponding to advances in standards of human immunodeficiency virus (HIV) disease care, including opportunistic infection prophylaxis, treatment with ART, and the prevention of mother-to-child transmission (pMTCT) of HIV. Per-person survival benefits for each era were determined using a mathematical simulation model. Published estimates provided the number of adult patients with new diagnoses of AIDS who were receiving care in the United States from 1989 to 2003.

Results. Compared with survival associated with untreated HIV disease, per-person survival increased 0.26 years with *Pneumocystis jiroveci* pneumonia prophylaxis alone. Four eras of increasingly effective ART in addition to prophylaxis resulted in per-person survival increases of 7.81, 11.05, 11.57, and 13.33 years, compared with the absence of treatment. Treatment for patients with AIDS in care in the United States since 1989 yielded a total survival benefit of 2.8 million years. pMTCT averted nearly 2900 infant infections, equivalent to 137,000 additional years of survival benefit.

Conclusions. At least 3.0 million years of life have been saved in the United States as a direct result of care of patients with AIDS, highlighting the significant advances made in HIV disease treatment.

In the face of the global AIDS pandemic, advancement in the treatment of HIV infection has been striking, but this progress has been associated with substantial economic costs. In 2006, US federal governmental agencies will allocate $21 billion to HIV/AIDS activities [1]. This includes ~$3 billion for HIV/AIDS research at the National Institutes of Health; $12.6 billion for treatment under Medicare and Medicaid and for Ryan White Care Act funds; $2.7 billion for global contributions; nearly $2 billion for cash and housing assistance; and almost $1 billion for prevention activities at the Centers for Disease Control and Prevention (CDC) and local health departments [1].

On 7 December 1995, the first protease inhibitor (PI), saquinavir, was approved by the US Food and Drug Administration, leading to the advent of highly active antiretroviral therapy (ART) for HIV disease. In light of the 10-year anniversary of this important breakthrough in HIV care, we sought to measure what 2 decades of medical research, patient care, and financial investment have produced in terms of overall survival gains. We employed a model-based approach, conducting repeated analyses to explore the clinical con-

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sequences of alternative patient-care-innovation pathways. Our objective was to quantify clinical progress in AIDS care, in terms of years of life saved as a result of advances in HIV therapies in the United States.

METHODS

Analytic overview. We defined 6 distinct eras of HIV/AIDS treatment from 1989 to 2003, reflecting advances in opportunistic infection (OI) prophylaxis and increasingly effective ART over time (figure 1) [2–12]. Using CDC surveillance and other published data, we estimated the number of patients with AIDS who received their diagnoses and entered care each year in the United States [13–15]. We used a previously developed computer simulation model of HIV disease to assess per-person survival gains for each treatment era, compared with survival in the absence of treatment [16–18]. Cumulative survival estimates for all patients who entered care were then calculated.

We also included 2 eras of maternal treatment for the prevention of mother-to-child transmission (pMTCT) of HIV (figure 1). Using CDC data on the number of HIV-infected women in the United States, as well as published birth, transmission, and survival rates for HIV-infected pediatric patients, we derived the number of infant infections averted and translated those into years of life saved [13, 19, 20].

This analysis was conservative; when assumptions were necessary, they were designed to underestimate the total survival benefit. For example, we limited the size of the eligible patient population to those with AIDS; we excluded the early benefits of antiretroviral mono- and dual-drug therapy when survival benefits were more limited and HIV RNA data were not available; we utilized lower estimates for rates of linkage to care; we assumed that those who did not access care in the first year of their AIDS diagnosis were never eligible; and we omitted any benefits of reduced HIV transmission from care. Sensitivity analyses were performed to examine the stability of the results in the face of alternative assumptions regarding delays in the adoption of clinical guidelines, mean CD4 cell count at presentation, the number of patients entering care, and ART efficacies.

Estimation of the sample population. Eligibility for therapy in any treatment era was limited to patients with CDC-defined AIDS; patients with non-AIDS HIV infection were excluded. Recognizing that not all patients with AIDS diagnoses receive timely care, we used national samples to estimate the proportion of patients entering care each year. National data suggest that 88% of eligible patients in the pre-ART era were receiving OI prophylaxis and that 57% of those in all of the ART eras were receiving appropriate comprehensive care [14, 15]. We characterized the newly diagnosed cohort as reflecting patients with advanced AIDS, with a mean CD4 cell count of 87 cells/mm^3 (SD, 70 cells/mm^3) and a mean HIV RNA level of 5.0 log copies/mL [5].

HIV disease model. The Cost-Effectiveness of Preventing AIDS Complications (CEPAC) model was used to estimate per-person survival benefits. CEPAC is a widely published computer-based state-transition simulation model of HIV disease that incorporates CD4 cell count; HIV RNA level; ART efficacy; OI incidence, treatment, and prophylaxis; and other important clinical information [16–18, 21]. "State transition" means that the model characterizes the progression of disease in an individual patient as a sequence of transitions from one "health state" to another.

Health states are defined along dimensions that are both descriptive of a patient's current well-being and predictive of future clinical events. These dimensions include CD4 cell count (>500, 301–500, 201–300, 101–200, 51–100, and ≤50 cells/mm^3) and HIV RNA level (>30,000, 10,001–30,000, 3001–10,000, 501–3000, and ≤500 copies/mL) [22]. In the model, the level of HIV RNA determines the rate of CD4 cell count decline, and the absolute CD4 cell count governs the monthly risk of OIs and death [16–18, 22].

In the model, HIV-infected patients are at risk for OIs (*Pneumocystis jiroveci* pneumonia [PCP], toxoplasmosis, *Mycobacterium avium* complex [MAC] disease, disseminated fungal in-

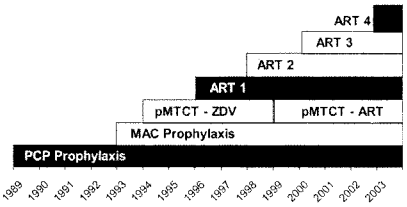


Figure 1. Timeline of major HIV interventions and when they became the standard of care in the United States. Six treatment eras were defined to correspond to the availability of improved therapies and changing standards of clinical care. The first 2 eras denote advances in opportunistic infection prevention, with prophylaxis for *Pneumocystis jirovecip*neumonia (PCP) starting in 1989 and prophylaxis for *Mycobacterium avium* complex (MAC) disease starting in 1993 [2–4]. Treatment with combination antiretroviral therapy (ART) was divided into 4 eras. ART 1 (1996–1997) marks the introduction of potent combination ART with the widespread use of protease inhibitor (PI)–based therapy [5]. ART 2 (1998–1999) includes the sequential use of nonnucleoside reverse transcriptase inhibitor–based regimens followed by PI-based unique regimens [6, 7]. From 2000 to 2002 (ART 3), 3 effective regimen options were available, with increased options for salvage through the use of resistance testing and ritonavir-boosted PIs [8, 10]. ART 4 (2003) included improved drug efficacy as reflected by increased tolerability, decreased regimen complexity, and the introduction of enfuvirtide [9–12]. We also considered 2 eras for the prevention of mother-to-child transmission (pMTCT): (1) zidovudine (ZDV) monotherapy alone, 1994–1999, and (2) combination ART, 2000 to present.

fection, cytomegalovirus infection, and bacterial and other infections) on the basis of their CD4 cell count [16, 23]. Patients receive the recommended standards of care in the year of their diagnosis, including regular CD4 cell count and HIV RNA laboratory tests and prophylaxis for PCP and MAC disease [24].

The model is able to accommodate a range of assumptions regarding the number of sequential lines of available ART, as well as their sequencing and efficacy. In the ART eras, patients whose CD4 cell count is <200 cells/mm^3 and are in care are eligible for ART. ART functions to suppress the HIV RNA level, producing a concomitant increase in CD4 cell count [5, 7, 8, 16]. The proportion of patients achieving virologic suppression while receiving each regimen is based on rates reported in the clinical trials and adjusted for lower suppression rates observed in nonclinical trial populations [5–12]. ART failure is defined as either virologic (an observed increase in HIV RNA level over 2 consecutive months) or clinical (the development of an OI). On failure of therapy, a subsequent regimen is initiated until all regimens available in that era are exhausted; the last line of therapy is continued after failure for its independent effect on averting OIs [25]. Rates of virologic suppression for ART are era specific, as described below.

Treatment with combination ART was divided into 4 eras. ART 1 (1996–1997) marks the introduction of potent combination ART with the widespread use of PI-based therapy [5]. ART 2 (1998–1999) includes the sequential use of nonnucleoside reverse-transcriptase inhibitor (NNRTI)–based regimens followed by PI-based unique regimens [6, 7]. From 2000 to 2002 (ART 3), 3 effective regimen options were available, with increased options for salvage through the use of resistance testing and ritonavir-boosted PIs [8, 10]. ART 4 (2003) included improved drug efficacy, as reflected by increased tolerability, decreased regimen complexity, and the introduction of enfuvirtide [9–12]. The literature-reported regimen suppression rates used for each ART era are provided in table 1.

Patients who initiate treatment in one era become eligible for additional therapies later, if they survive to subsequent eras. Reflecting diminishing ART efficacy with increasing ART experience, these later regimens may differ in their suppression rates from those that would be available to patients who initiate therapy in the subsequent era.

Hypothetical patients with AIDS enter the model one at a time and are followed until death. A cohort of 1 million patients was simulated, to obtain stable results; summary statistics for the analysis included average numbers of OIs and per-person life expectancy. For each year of AIDS diagnosis from 1989 to 2003, one cohort was simulated with no treatment and the second was simulated with all treatment interventions available during that era; the 2 cohorts' average life expectancies were then compared, to obtain the net treatment benefit for the cohort that received diagnoses in that year. Survival curves generated from the model were validated against CDC-reported survival curves [13].

Model input data. Detailed data for model input are provided in table 1 [2–12, 19, 20, 22, 23, 26–29]. Briefly, OI prophylaxis efficacy is based on published data and is defined as the percentage reduction in the monthly risk of OIs: 98.2% for PCP and 77.2% for MAC disease [2–4]. Rates of virologic suppression for ART are era specific, both for the initial treatment regimen and for the subsequent regimens that are available after drug resistance or poor adherence causes the initial regimen to fail. For example, data for those patients who receive diagnoses in ART 1 (or before then, if they are still alive at the beginning of ART 1) are derived from a trial of a triple-combination regimen that reported HIV RNA suppression in 60% of patients at 24 weeks [5]. This efficacy is reflective of a cohort of patients, all of whom were pretreated with zidovudine alone [5]. Among those still alive by ART 2, efficacy is derived from a second-line efavirenz-based regimen in patients pretreated with nucleoside reverse-transcriptase inhibitors (NRTIs), which achieves 60% suppression at 48 weeks [6]. For those who remain alive in ART 3 and ART 4, third- and fourth-line treatment options become available, with efficacy derived from trials showing suppression rates of 34% at 12 weeks and 30% at 48 weeks, respectively [8, 9]. All reported efficacies are extrapolated to 48 weeks, as reported elsewhere [17]. Because the reported treatment efficacies of available regimens are from clinical trials and may overstate clinical cohort efficacies, we reduced the 48-week efficacy of suppression for each regimen by a factor of 15%. This relative reduction in efficacy represents reported differences in suppression efficacies between an observational Medicaid cohort and a clinical trial population receiving a comparable NNRTI-based regimen at a similar disease stage [11, 30].

pMTCT. To estimate survival gains attributable to pMTCT, the number of HIV-infected women in the United States was obtained from CDC surveillance data [13]. Birth rates; rates of ART utilization; HIV vertical transmission rates with no treatment (25.5%), with peripartum zidovudine treatment (8.3%), and with combination ART (3.0%); and life expectancies for HIV-infected infants are provided in table 1 [19, 20, 26, 27]. Children born HIV negative were assigned age- and race-adjusted life expectancies based on US life tables [31].

RESULTS

Per-person HIV disease treatment survival benefits among those receiving care. Results from the era of PCP prophylaxis alone show that mean per-person life expectancy increased by 3.1 months, compared with that in the absence of prophylaxis (table 2). In this era, 33% of patients survived to 1993 (the PCP and MAC disease prophylaxis era), but only 2% survived to 1996 to receive any highly active ART. Although the life expectancy benefit anticipated from PCP and MAC disease pro-

Table 1. Data for model inputs and prevention of mother-to-child transmission (pMTCT) estimations.

Variable	Estimate	Reference
Initial cohort		
CD4 cell count, mean ± SD, cells/mm^3	87 ± 70	[5]
HIV RNA level, mean ± SD, $\log_{10}$ copies/mL	5.0 ± 0.6	[5]
Monthly CD4 cell count decrease by HIV RNA stratum, mean, cells/mm^3		
>30,000 copies/mL	6.4	[22]
10,001–30,000 copies/mL	5.4	[22]
3001–10,000 copies/mL	4.6	[22]
501–3000 copies/mL	3.7	[22]
≤500 copies/mL	3.0	[22]
Monthly risk of OI when CD4 cell count is <50 cells/mm^3, %[a]		
PCP	0.03700	[23]
MAC disease	0.01220	[23]
Toxoplasmosis	0.00270	[23]
Cytomegalovirus infection	0.01857	[23]
Fungal infections	0.01123	[23]
Other	0.03940	[23]
OI prophylaxis efficacy,[b] %		
PCP prophylaxis	98.2	[2]
MAC disease prophylaxis	77.2	[3, 4]
Rates of virologic suppression[c]		
ART 1	**60% at 24 w**	[5]
	[60% at 48 w]	[6]
	[34% at 12 w]	[8]
	[30% at 48 w]	[9]
ART 2	**70% at 48 w**	[7]
	60% at 48 w	[6]
	[34% at 12 w]	[8]
	[30% at 48 w]	[9]
ART 3	**70% at 48 w**	[7]
	81% at 24 w	[10]
	34% at 12 w	[8]
	[30% at 48 w]	[9]
ART 4	**80% at 48 w**	[11]
	82% at 24 w	[10]
	56% at 48 w	[12]
	30% at 48 w	[9]
pMTCT		
Pregnancy rate in HIV-infected women, %	4.4–6.3	[26]
Birth rate in HIV-infected women, %	36.0	[27]
Vertical transmission rate with no perinatal ZDV, %	25.5	[19]
Vertical transmission rate with perinatal ZDV, %	8.3	[19]
Vertical transmission rate with combination ART, %	3.0	[20]
Perinatal ZDV use, %		
1994–1995	78	[20]
1996–1999	71	[20]
2000–2003	9	[20]
Perinatal combination ART use, %		
1994–1995	0	[20]
1996–1999	6	[20]
2000–2003	70	[20]
Infant survival with HIV infection pre-ART, years	10.9	[28]
Infant survival with HIV infection post-ART, years	27.0	[29]

NOTE. MAC, *Mycobacterium avium* complex; OI, opportunistic infection; PCP, *Pneumocystis jiroveci* pneumonia; ZDV, zidovudine.

[a] Percentage risk in the absence of prophylaxis and antiretroviral therapy (ART).

[b] Efficacy defined as percentage reduction in monthly risk of infection.

[c] Antiretroviral suppression rates and time points are provided for the trial from which they were derived. For modeling purposes, these rates were extrapolated to 48 weeks and decreased by a relative 15% for model input. Regimens that were available in each era are shown in bold. Patients surviving to subsequent eras were eligible for therapy at efficacies shown in brackets.

phylaxis alone was just 2.6 months, the era of PCP and MAC disease prophylaxis led to a mean survival increase of 24.4 months. This increase is largely a result of 39% of this cohort surviving to 1996 and then benefiting from ART 1. PCP and MAC disease prophylaxis combined with ART 1, 2, and 3 resulted in mean per-person survival increases of 93.7, 132.6, and 138.8 months, respectively. By ART 4 (2003), comprehensive AIDS care resulted in a projected per-person survival gain of 159.9 months, or 13.3 years.

HIV disease treatment survival benefits. The number of patients entering care in the United States ranged from a maximum of 75,486 per year in the PCP and MAC disease prophylaxis era (1993–1995) to a minimum of 24,780 in ART 4 (2003). The total survival benefit ranged from 40,912 years in the PCP prophylaxis era to 832,179 years in ART 3. The cumulative survival benefit for AIDS-related OI prophylaxis and combination ART was 2,813,892 years. Of these, 1,184,851 years have already been realized, and 1,629,041 years are being accrued by current patients with AIDS in care. Model-based survival curves for patients who received diagnoses in the first year of each of the 6 treatment eras (1989, 1993, 1996, 1998, 2000, and 2003) illustrate the improvement in AIDS-associated survival in the United States over time (figure 2). Median survival was 1.7 years for the PCP era, 7.5 years for ART 1, and 14.1 years for ART 4.

pMTCT survival benefits. pMTCT produced notable survival benefits as well. In the zidovudine-alone era (1994–1999), perinatal zidovudine treatment averted 1056 infant infections

Table 2. Per-person survival benefits, numbers of patients with AIDS entering care, and era-specific and cumulative survival benefits.

Year	Intervention	Per-person survival benefit[a]	Patients with AIDS entering care, no.	Patients surviving to next treatment era, %	Infections averted, no.	Total survival benefit, years
HIV disease treatment						
1989–1992	PCP prophylaxis	3.1 mo	158,370	33	...	40,912
1993–1995	PCP/MAC prophylaxis	24.4 mo	226,458	39	...	460,465
1996–1997	PCP/MAC prophylaxis +ART 1	93.7 mo	72,716	86	...	567,788
1998–1999	PCP/MAC prophylaxis +ART 2	132.6 mo	52,702	93	...	582,359
2000–2002	PCP/MAC prophylaxis +ART 3	138.8 mo	71,946	91	...	832,179
2003	PCP/MAC prophylaxis +ART 4	159.9 mo	24,780	...	...	330,189
Subtotal						2,813,892
pMTCT						
1994–1999 (pMTCT-ZDV)	Child receives OI prophylaxis and ZDV monotherapy	60.5 years	...	...	223	51,646
1994–1999 (pMTCT-ZDV)	Child receives OI prophylaxis and combination ART	45.8 years	...	...	833	
2000–2003 (pMTCT–combination ART)	Child receives OI prophylaxis and combination ART	46.7 years	...	...	1839	85,833
Subtotal						137,479
Total						2,951,371

NOTE. ART, antiretroviral therapy; MAC, *Mycobacterium avium* complex; OI, opportunistic infection; PCP, *Pneumocystis jiroveci;* pMTCT, prevention of mother-to-child transmission; ZDV, zidovudine.

[a] Survival benefits reflect changes in both the life expectancy of HIV-positive patients and the general US population over time. Per-person survival benefit is reported as a weighted average of the per-person survival benefit among those receiving care derived from each year in the era.

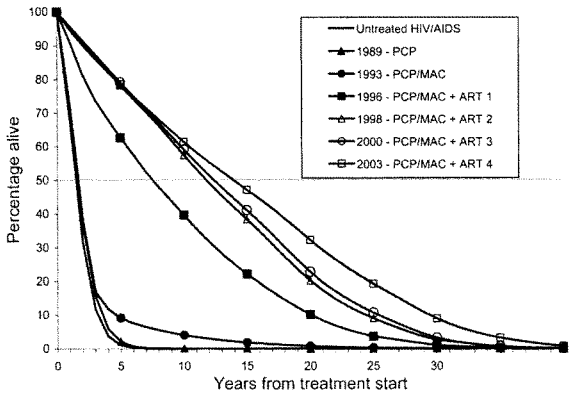


Figure 2. Survival curve produced by model simulations of the cohort that received diagnoses in the first year of each treatment era, with a mean age at treatment start of 39 years (SD, 9 years). ART, antiretroviral therapy; MAC, *Mycobacterium avium* complex; PCP, *Pneumocystis jiroveci* pneumonia.

(table 2). After 2000, when combination ART became widely used in pregnant women, 1839 infant infections were averted. Mean per-child survival gains for the averted infections ranged from 60.5 years if the child was born before 1996 (before combination ART) to 45.8 years during 1996–1999, when combination ART was available. pMTCT led to a survival benefit of 137,479 years (table 2).

The cumulative survival benefit of AIDS-related OI prophylaxis, combination ART, and pMTCT in the United States was 2,951,371 years.

Sensitivity analyses. Several sensitivity analyses were performed to examine the stability of the results. When we assumed that the changes in standards of care might take 1 year to implement (as may occur for patients treated in lower-volume centers), total survival benefits decreased to 2.4 million years. When we examined the impact of alternative, less widely accepted estimates of the rate of vertical transmission associated with ART [32], estimated survival benefits due to pMTCT fell from 137,479 to 99,680 years.

We also relaxed the conservative estimates in sensitivity analyses. When we used the full reported efficacy of ART from the clinical trials [11, 30], per-person survival gains in ART 4 increased from 159.9 to 188.8 months, and total survival gains increased by 500,000 years. When we assumed that linkage to care was not 57% but as high as 76% [15], survival gains increased by 710,000 years. As a surrogate for earlier presentation to care, a healthier AIDS cohort—with a mean CD4 cell count of 175 cells/mm^3—was also examined, since, after 1992, ~70% of new AIDS diagnoses were made according to a CD4 cell count criterion of <200 cells/mm^3 alone [33]. Cumulative survival benefits in this scenario increased by 740,000 years. Simultaneously relaxing all of these conservative assumptions resulted in a total survival benefit of >5.2 million years.

DISCUSSION

We utilized national surveillance data, efficacy data, and a state-transition probability model to estimate the survival benefits of AIDS therapy in the United States. This type of analysis does not lend itself readily to traditional forms of scientific investigation, since there is no counterfactual to the history of AIDS treatment in reality. Projected per-person survival after an AIDS diagnosis increased from 19 months (1.6 years) in the absence of treatment to 179 months (14.9 years) by 2003, a gain of 160 months (13.3 years). This survival benefit greatly exceeds that achieved for patients with many other chronic diseases in the United States [34–42]. Although this type of analysis has not been conducted for many diseases, we have synthesized data from the literature to estimate life-expectancy gains for patients with other severe and chronic diseases (figure 3). For example, chemotherapy for non–small-cell lung cancer results in an average survival benefit of 7 months, and bone marrow transplantation for relapsed non-Hodgkins lymphoma is associated with a survival benefit of 92 months [34, 41, 42]. Early in the course of the pandemic, OI prophylaxis had a profound impact on changing the face of AIDS and on shaping the perception that HIV disease was treatable [43]. However, the current magnitude of the life-expectancy gain from AIDS treatment is

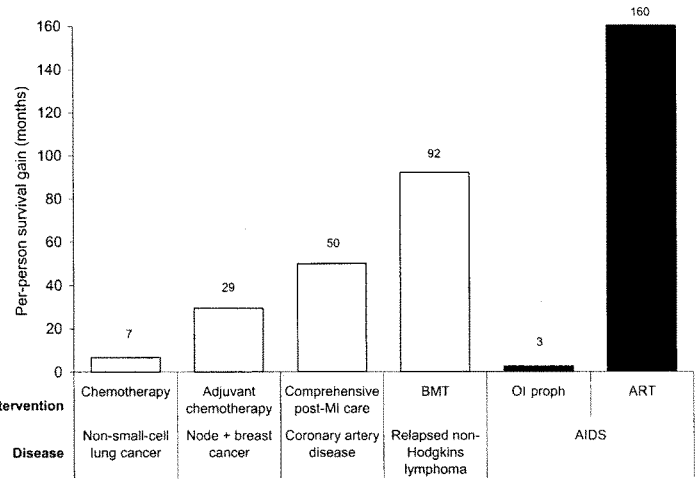


Figure 3. Per-person survival gains for patients with various interventions for chronic diseases in the United States [34–42]. Opportunistic infection prophylaxis (OI proph) confers a 3-month benefit (if no benefit to antiretroviral therapy [ART] in those eras is assumed). ART produces 160 months of per-person survival gain by the year 2003. BMT, bone marrow transplant; MI, myocardial infarction.

largely attributable to combination ART; this has transformed AIDS from a fatal disease to a highly treatable chronic condition, with average survival from AIDS diagnosis that is now >14 years.

As many as 312,000 of the estimated 1,185,000 people infected with HIV in the United States are thought to be unaware of their serostatus [44]. Of those who are aware of their infection, only 57% are estimated to be in care [15]. Using a cohort of patients with higher CD4 cell counts as a surrogate for earlier diagnosis and linkage to care, we found that an additional 740,000 years of life might have been saved, had all patients with AIDS in the United States received appropriate treatment on diagnosis. Thus, our findings not only demonstrate the striking survival gains achieved via advances in AIDS treatment but also emphasize the importance of expanded HIV testing and linkage to care, so that greater numbers of infected persons can access lifesaving therapy.

Previous work using the same HIV disease model estimated that, in 1996, ART led to per-person survival benefits of 18.5 months [16]. Updated results from the current analysis suggest that mean survival increases from the same era (ART 1) were 93.7 months. The additional 75.2 months reflects the value of new HIV therapies that have been developed and are available for patients receiving failing regimens. Our results are also consistent with those demonstrating the effectiveness of current ART in large cohort studies, in which the median AIDS-associated survival was found to be extended by 14.8 years [45].

This analysis has several limitations. Patients entering ART 1 often were mono-drug– or dual-drug–therapy experienced. We addressed this problem by modeling early treatment efficacy rates on the basis of patients who had received zidovudine monotherapy [5]. To match estimates in clinical cohorts rather than clinical trials, we decreased the reported efficacy rates from all trials by an additional 15% [11, 30]. Estimating the year of entry into care compared with the year of AIDS diagnosis was a challenge; we conservatively limited the eligible patients entering care each year, reduced their assumed state of health (mean CD4 cell count, 87 cells/mm^3), and assumed that those who did not access care in the year of diagnosis were never eligible for care.

The analysis did not account for later ART-related toxicities that may result in, for example, cardiac disease or diabetes [46]. This exclusion is unlikely to have had a major impact on the analysis. Although the relative risk of cardiac disease may be increased as a result of ART, this increase is greatly outweighed by the absolute reduction in the risk of AIDS-related complications from ART [47]. Previous work estimating HIV treatment–induced changes in lipid levels suggests that hyperlipidemia reduces overall life expectancy by ~1 month [48].

Early reports of OI prophylaxis and ART efficacy in less-

developed countries have suggested that the per-person survival gains in these settings may be comparable to those in the United States, even in the absence of customized, highly monitored care [49]. With 38 million HIV-infected people worldwide, the increased availability of ART through the WHO-sponsored "3 by 5" initiative, as well as through the President's Emergency Plan for AIDS Relief (PEPfAR) and other sources, has the potential to save hundreds of millions of years of life in the global setting and speaks to the imperative to deliver treatment to individuals in these countries quickly and efficiently [50, 51].

HIV disease has claimed >20 million lives worldwide and more than half a million lives in the United States alone [13, 51]. Our analysis demonstrates the striking scientific and clinical benefits achieved in the fight against this disease. Ten years after the introduction of potent combination ART, at least 3 million years of life have been saved in the United States.

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Millions of Life-Years Saved with Potent Antiretroviral Drugs in the United States: A Celebration, with Challenges

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(See the article by Walensky et al., on pages 11–9.)

In this issue of the *Journal*, Walensky et al. estimate the benefits that have been gained from multidrug antiretroviral therapies (ARTs) since 1989 [1]. Their finding of ~3 million years of life saved in the United States quantifies ART benefits at the population level, complementing the well-known data on plummeting US death rates and lower AIDS case report rates noted in the era of potent therapy [2, 3]. The authors' detailed sensitivity analyses, varying key estimated parameters in their models, indicate that less-conservative assumptions generate an estimate of >5 million years of life saved, a plausible "higher-end" estimate of benefit. The typical HIV-infected person now receiving potent combination ART lives at least 13–14 years longer than if he or she were to forego this therapy or if it were otherwise unavailable [1]. Quantifying the survival benefits of expanded diagnosis and modern care suggests that the economic and humanitarian benefits are greater than were hitherto appreciated.

Developing drugs, testing them without undue delay, accelerating their regulatory approval, and making them widely available have saved lives (table 1). That an average of ~200,000 persons in the United States have lived an additional year in each of the past 15 years suggests the gift given to those in need from the labor of many [1]. Drugs are discovered and developed by biochemists, pharmaceutical developers, animal modelers, formulation chemists, microbiologists, pharmacologists, and many others in the pharmaceutical industry, in academia, at research institutes, and in government. Drugs are tested for safety and efficacy by clinical-trials experts, research-study nurses, clinical-trials volunteers, community activists, government scientists and science managers, community workers, health-care providers, pharmacists, ethical-review staff, and allied health workers. After drug approval through the work of pharmaceutical companies and regulatory-oversight experts, implementation depends on health-care workers, blood bankers, social workers, mental-health professionals, substance-abuse treatment providers, journalists, science writers, medical editors, spiritual leaders, corporate and small business leaders, enlightened insurers, and family and friends of patients challenged to receive lifelong polypharmacy. (Of course, our public-health workers in health education and promotion, epidemiology, and community prevention efforts are credited, together with community prevention activists, for laboring to reduce the need for these drugs altogether.) Political and policy leaders influence research and care investments even as health activists push the system to be more responsive and efficient. Central to implementation are the HIV-infected persons themselves, who, by the tens of thousands, keep their appointments, take pills, eliminate or reduce high-risk behaviors, and support peers who struggle with the promising but complex world of daily, lifelong therapy. The model of Walensky et al. gives all of us, from our complementary disciplines, cause for celebration.

Zidovudine was the first approved antiretroviral agent, offering benefits that were exciting but, ultimately, only transient, because of the HIV drug resistance resulting from monotherapy [4–8]. Walensky et al. have assumed a small contribution from *Pneumocystis jiroveci* prophylaxis but no net benefit from zidovudine monotherapy alone, presumably on the basis of the results of the European Concorde study [8]. Their latter assumption is debatable [6, 9–11]. Inclusion of survival benefits from zidovudine monotherapy would increase the lives-saved calculus—another conservative bias, in any case. Dual therapy proved to be much superior to monotherapy, and triple therapy was a huge advance, in turn, over the use of 2 drugs [12, 13]. This research progress and its health impact, as documented by

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Table 1. Brand-name drugs approved by the US Food and Drug Administration as of March 2006 for use in the treatment of HIV infection.

Drug type, brand name	Generic name	Manufacturer	Approval date	Time to approval, months
NRTIs				
Combivir	Lamivudine and zidovudine	GlaxoSmithKline	27 Sep 1997	3.9
Emtriva	Emtricitabine	Gilead Sciences	2 Jul 2003	10
Epivir	Lamivudine	GlaxoSmithKline	17 Nov 1995	4.4
Epzicom	Abacavir and lamivudine	GlaxoSmithKline	2 Aug 2004	10
Hivid	Zalcitabine	Hoffmann–La Roche	19 Jun 1992	7.6
Retrovir	Zidovudine	GlaxoSmithKline	19 Mar 1987	3.5
Trizivir	Abacavir, zidovudine and lamivudine	GlaxoSmithKline	14 Nov 2000	10.9
Truvada	Tenofovir disoproxil fumarate and emtricitabine	Gilead Sciences	2 Aug 2004	5
Videx EC	Enteric-coated didanosine	Bristol-Myers Squibb	31 Oct 2000	9
Videx	Didanosine	Bristol-Myers Squibb	9 Oct 1991	6
Viread	Tenofovir disoproxil fumarate	Gilead	26 Oct 2001	5.9
Zerit	Stavudine	Bristol-Myers Squibb	24 Jun 1994	5.9
Ziagen	Abacavir	GlaxoSmithKline	17 Dec 1998	5.8
NNRTIs				
Rescriptor	Delavirdine	Pfizer	4 Apr 1997	8.7
Sustiva	Efavirenz	Bristol-Myers Squibb	17 Sep 1998	3.2
Viramune	Nevirapine	Boehringer Ingelheim	21 Jun 1996	3.9
Protease inhibitors				
Agenerase	Amprenavir	GlaxoSmithKline	15 Apr 1999	6
Aptivus	Tipranavir	Boehringer Ingelheim	22 Jun 2005	6
Crixivan	Indinavir	Merck	13 Mar 1996	1.4
Fortovase	Saquinavir	Hoffmann–La Roche	7 Nov 1997	5.9
Invirase	Saquinavir mesylate	Hoffmann–La Roche	6 Dec 1995	3.2
Kaletra	Lopinavir and ritonavir	Abbott Laboratories	15 Sep 2000	3.5
Lexiva	Fosamprenavir calcium	GlaxoSmithKline	20 Oct 2003	10
Norvir	Ritonavir	Abbott Laboratories	1 Mar 1996	2.3
Reyataz	Atazanavir sulfate	Bristol-Myers Squibb	20 Jun 2003	6
Viracept	Nelfinavir mesylate	Agouron Pharmaceuticals	14 Mar 1997	2.6
Fusion inhibitors				
Fuzeon	Enfuvirtide	Hoffmann–La Roche and Trimeris	13 Mar 2003	6

NOTE. NNRTIs, nonnucleoside reverse-transcriptase inhibitors; NRTIs, nucleoside reverse-transcriptase inhibitors. Modified slightly from http://www.fda.gov/oashi/aids/virals.html. The relevant Web page is available at http://www.fda.gov/oashi/aids/status.html.

Walensky et al., can be seen as a continuum dating from the discovery of the syndrome in 1981 and of the virus in 1983 through the successive approval of each of the 4 drug classes since 1987 (table 1). This latter-20th-century advance in antiviral therapy has its centennial parallel in the golden era of microbiology and vaccine and drug development in the late 19th and early 20th centuries. Of course, Pasteur, Koch, and their peers were empiricists with little grasp of the microbiology known today [14]; 21st century grounding in molecular methods augurs well for future discoveries leading to an eventual cure for HIV infection, flushing out and killing virus that is latent in deep tissues. This may be a good time for our national political leaders to reconsider their decision to slow the growth of the budget of the US National Institutes of Health, now lagging behind the rate of inflation [15, 16].

Use of ART to block HIV transmission from mother to infant has virtually eliminated pediatric HIV infection as a major public-health problem in the United States and other economically prosperous nations [17, 18]. Easier-to-implement nevirapine and nevirapine-zidovudine regimens were developed that could be applied anywhere in the world, as with the "Call to Action" program (sponsored by the Elizabeth Glaser Pediatric AIDS Foundation and the Bill and Melinda Gates Foundation) and the Thai government initiative [19–22]. Drugs suitable for treating pediatric-age patients with HIV infection are readily available in the United States (table 2) but are less so in resource-limited nations.

In the late 1990s, activists cajoled the pharmaceutical industry into lower drug prices. Combined with lower drug prices

Table 2. Drugs used in the treatment of pediatric HIV infection, per the US Food and Drug Administration as of March 2006, listed alphabetically by brand name.

Brand name	Generic name	Manufacturer	Approval date	
			Adult	Pediatric[a]
Agenerase	Amprenavir	GlaxoSmithKline	15 Apr 1999	15 Apr 1999
Combivir	Zidovudine and lamivudine	GlaxoSmithKline	26 Sep 1997	None
Crixivan	Indinavir	Merck	13 Mar 1996	None
Emtriva	Emtricitabine	Gilead Sciences	2 Jul 2003	28 Sep 2005
Epivir	Lamivudine	GlaxoSmithKline	17 Nov 1995	17 Nov 1995
Fortovase	Saquinavir	Roche	7 Nov 1997	None
Hivid	Zalcitabine	Roche	19 Jun 1992	None
Invirase	Saquinavir	Roche	6 Dec 1995	None
Kaletra	Lopinavir and ritonavir	Abbott Laboratories	15 Sep 2000	15 Sep 2000
Norvir	Ritonavir	Abbott Laboratories	1 Mar 1996	14 Mar 1997
Rescriptor	Delavirdine	Pfizer	4 Apr 1997	None
Retrovir	Zidovudine	GlaxoSmithKline	19 Mar 1987	1 May 1990
Sustiva	Efavirenz	Bristol-Myers Squibb	21 Sep 1998	21 Sep 1998
Videx	Didanosine	Bristol-Myers Squibb	9 Oct 1991	9 Oct 1991
Viracept	Nelfinavir	Agouron Pharmaceuticals	14 Mar 1997	14 Mar 1997
Viramune	Nevirapine	Boehringer Ingelheim	21 Jun 1996	11 Sep 1998
Viread	Tenofovir disoproxil fumarate	Gilead	26 Oct 2001	None
Zerit	Stavudine	Bristol-Myers Squibb	24 Jun 1994	6 Sep 1996
Ziagen	Abacavir	GlaxoSmithKline	17 Dec 1998	17 Dec 1998

NOTE. Modified slightly from http://www.fda.gov/oashi/aids/pedlbl.html. The relevant Web page is available at http://www.fda.gov/oashi/aids/status.html.

[a] "None" indicates no pediatric labeling; although these drugs may be used by practitioners in the treatment of children of various ages, the pharmaceutical sponsors have not submitted data to support a labeled pediatric indication at this time.

due to competition from producers of generic drugs (including in the United States) (table 3), a major effort to provide ART to infected persons in developing countries began through multinational (e.g., the Global Fund to Fight AIDS, Tuberculosis, and Malaria [http://www.theglobalfund.org/en/]), bilateral (e.g., the President's Emergency Program for AIDS Relief [http://www.usaid.gov/our_work/global_health/aids/pepfarfact.html]), and national (e.g., the ahead-of-its-time program in Brazil) initiatives [23, 24]. These are lowering HIV mortality rates in resource-limited settings, just as they did earlier in the economically richer nations [25]. A lethal disease has been transformed into a chronic, manageable condition wherever health services delivery, financing, drug logistics (especially critical in rural areas and developing countries), health manpower, health policy, and health psychology are applied successfully.

Walensky et al. highlight the importance of detecting all persons infected and providing care to all those who know their HIV status [1]. Innovation is needed on many fronts. The state of North Carolina identifies acutely infected, hyperinfectious persons, to provide them with risk-reduction counseling even before antibodies are detectable [26]. Brief health education messages that are designed for clinicians to deliver within the care setting have assisted persons in HIV care to reduce their high-risk behaviors [27]. Practitioners in lower-prevalence regions suggest minimizing pretest counseling through interview-based risk triage, reserving their staff time for the essential posttest counseling sessions [28]. Rapid tests are used widely in developing-world settings to cut costs

Table 3. Generic nucleoside reverse-transcriptase inhibitors approved by the US Food and Drug Administration as of March 2006 for use in the treatment of HIV infection.

Generic name (dose)	Manufacturer	Approval date	Time to approval, months
Didanosine delayed-release capsule	Barr Laboratories	3 Dec 2004	6
Oral solution zidovudine (pediatric formulation, 50 mg/5 mL)	Aurobindo Pharma	19 Sep 2005	6
Zidovudine (300-mg tablet)	Aurobindo Pharma	19 Sep 2005	10
Zidovudine (300-mg tablet)	Ranbaxy Laboratories	19 Sep 2005	11
Zidovudine (300-mg tablet)	Roxane Laboratories	19 Sep 2005	24
Zidovudine (100-mg capsule)	Aurobindo Pharma	27 Mar 2006	4

NOTE. Modified slightly from http://www.fda.gov/oashi/aids/viralsgeneric.html. The relevant Web page is available at http://www.fda.gov/oashi/aids/status.html.

and avoid the loss to follow-up inherent in an ELISA screening (a result of the inability to provide a same-day result with an ELISA). Rapid tests are an innovation used far less often in the United States than they should be [29]. Antenatal care programs should offer "opt-out" testing—that is, HIV testing that is routine in pregnant women, excluding only those women actively requesting to forego the test [30, 31]. Efforts to increase voluntary counseling and testing and knowledge of HIV status include couples counseling to reduce marital strife and to maximize family-centered care and prevention [32–34]. These are but a few examples of innovations in the diagnosis, care, and prevention of HIV infection.

Drugs that save lives are likely to save society money, because it is cheaper to care for persons with drugs in an outpatient setting than to care for them in intensive care units, acute-care hospital beds, long-term care facilities, and hospices [35–37]. Restoring economic productivity and parent-based child care saves so-called indirect costs, and fewer emergency-department visits and hospital stays save direct costs to the health-care system. Further investment in outpatient care should emphasize voluntary counseling and testing programs for HIV diagnosis that are integrated into routine medical care [38]. This must include bridges to care for those infected. The humanitarian benefits are self-evident but may not drive investment as strongly as economic arguments can. Savings may accrue to one provider (e.g., reduced unreimbursed inpatient care expenses to a hospital or lower third-party payments), but costs may be incurred by another source (e.g., Ryan White Care Act funds). Hence, policy makers may see only their costs without knowledge of direct benefits or the savings in a different bailiwick. Early indications are that savings from outpatient management substantially outweigh the costs of the ART-based outpatient treatment programs, both here in the United States and abroad, but good data are scarce [39].

The millions of life-years saved in the United States should reinvigorate policy debates as to how best to identify HIV-infected persons in our country by offering and encouraging testing as a routine part of medical screening. We must reduce barriers to care, the first of which is the difficulty with which a test is obtained in many venues. We do not require extensive, expensive, time-consuming, and intimidating pretest counseling before screening for diabetes, for example, another disease that is lethal if unmanaged but that is controllable with lifelong medication. Yet many US guidelines demand substantial counseling infrastructures that may discourage primary-care providers from offering HIV tests as easily as they can offer a urine dipstick for glucose to screen for diabetes. Posttest counseling is essential for psychosocial assistance, a bridge to HIV-related health care, and needed to reduce high-risk behaviors, but pretest counseling can be made more efficient to reduce at least one barrier of time and money [28, 38].

We now face a daunting challenge to do better. From 3 to 5 million person-years of life have been saved for persons living in the United States from 1989 to 2003, but do we know enough about the barriers to prompt diagnosis and effective referral to care? Are we doing enough about those barriers that we do recognize? If we address systematically the barriers to testing, care, and prevention, then future modelers will describe the *next* 15-year period as having saved *hundreds* of millions of life-years, not just in North America but around the globe.

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MAJOR ARTICLE HIV/AIDS

Distribution of Health Care Expenditures for HIV-Infected Patients

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(See the editorial commentary by Mayer and Chaguturu on pages XXX–XX)

Background. Health care expenditures for persons infected with human immunodeficiency virus (HIV) in the United State determined on the basis of actual health care use have not been reported in the era of highly active antiretroviral therapy.

Methods. Patients receiving primary care at the University of Alabama at Birmingham HIV clinic were included in the study. All encounters (except emergency room visits) that occurred within the University of Alabama at Birmingham Hospital System from 1 March 2000 to 1 March 2001 were analyzed. Medication expenditures were determined on the basis of 2001 average wholesale price. Hospitalization expenditures were determined on the basis of 2001 Medicare diagnostic related group reimbursement rates. Clinic expenditures were determined on the basis of 2001 Medicare current procedural terminology reimbursement rates.

Results. Among the 635 patients, total annual expenditures for patients with $CD4^+$ cell counts <50 cells/μL ($36,533 per patient) were 2.6-times greater than total annual expenditures for patients with $CD4^+$ cell counts ≥350 cells/μL ($13,885 per patient), primarily because of increased expenditures for nonantiretroviral medication and hospitalization. Expenditures for highly active antiretroviral therapy were relatively constant at ~$10,500 per patient per year across $CD4^+$ cell count strata. Outpatient expenditures were $1558 per patient per year; however, the clinic and physician component of these expenditures represented only $359 per patient per year, or 2% of annual expenses. Health care expenditures for patients with HIV infection increased substantially for those with more-advanced disease and were driven predominantly by medication costs (which accounted for 71%–84% of annual expenses).

Conclusions. Physician reimbursements, even with 100% billing and collections, are inadequate to support the activities of most clinics providing HIV care. These findings have important implications for the continued support of HIV treatment programs in the United States.

The use of HAART has led to dramatic decreases in the morbidity and mortality of patients infected with HIV [1–3]. These benefits, however, come with the expense of HAART, estimated to be $10,000–$15,000 per patient per year in the United States [4]. A number of studies have estimated the monthly health care expenditures incurred by HIV-infected patients and have investigated the relationship between these expenditures and $CD4^+$ cell counts [5–15]. Yet, there is no information determined on the basis of actual health care use, in quantitative terms, regarding actual expenditures in the contemporary HAART era. Moreover, no prior studies have been able to evaluate the annual expenditures for a patient whose $CD4^+$ cell count increases or decreases during the course of therapy.

We investigated questions related to the relationship among the cost components of care and examined how a change in clinical status affected cost expenditures over a period of 1 year. Answers to these questions, determined in the context of the contemporary HAART era, are essential if policy makers and third-party payers are to make informed decisions about the optimal allocation of scarce resources. To address these questions, we performed an analysis of expenditures using the University of Alabama at Birmingham (UAB) Studies

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Table 1. Cost components and expenditures included in a study of patients with HIV infection at the University of Alabama at Birmingham.

Cost component	Expenditures	Cost data
Hospital costs	Inpatient medications, radiological examinations, laboratory studies, and procedures, by Medicare reimbursement rates for diagnostic related group codes	Medicare diagnostic related group, based on hospital diagnoses
Antiretroviral medications	Outpatient antiretroviral medications, by average wholesale price	Average wholesale price, using stop and start dates per drug
Nonantiretroviral medications	All nonantiretroviral outpatient medications, including antibiotics, by average wholesale price	Average wholesale price, using stop and start dates per drug
Physician/clinic fees	Physician fees included inpatient and outpatient physician professional fees; clinic fees included medication services (i.e., infusions, injections, and chemotherapy) and charges for use of space	Medicare reimbursements paid via current procedural terminology codes for visit
Other outpatient expenditures	Outpatient procedures not performed in the HIV outpatient clinic (i.e., laboratory studies, radiological examinations, and outpatient surgeries), home health care, and hospice care	Medicare reimbursements paid via current procedural terminology codes

of HIV/AIDS Longitudinal Outcome Metrics database. This database combines clinical data, laboratory data, and data on health care use for all of its patients to monitor and measure outcomes of care over time. Therefore, this database provides the opportunity to investigate the relationship between health care expenditures and $CD4^+$ cell counts, to evaluate the contribution of each category of expenditures to overall expenditures, and to quantitate the effect of an increase or decrease in $CD4^+$ cell count on expenditures.

METHODS

In January 1994, the UAB outpatient HIV clinic initiated an ongoing database (Studies of HIV/AIDS Longitudinal Outcome Metrics) that collected clinical information for all patients seen. Trained medical records personnel used standardized procedures to abstract clinical and treatment data from medical records daily. Laboratory data were downloaded from the hospital laboratory system directly into the database. All outside laboratory values were entered into the database manually (quality control assessments demonstrated an error rate of <5%). Health care use data were added to the database beginning in March 1999.

All patients included in this study received their primary care at the UAB HIV clinic, had a baseline $CD4^+$ cell count on 1 March 2000 ($\pm$90 days), and had at least 1 follow-up clinic visit or hospitalization between 1 June 2000 and 1 March 2001. Patients who had a follow-up visit after 1 June 2000 but subsequently died before 1 March 2001 were also included.

Hospitalization, laboratory, procedure, and clinic use data were obtained from the UAB Health System between 1 March 2000 and 1 March 2001; data pertaining to emergency department visits that did not result in an inpatient admission were not included. Health care received outside of the UAB health system was not captured. An expenditure was defined as the cost outlay required to pay for any service or medication used by a patient during the time of observation. Information on use of clinical services was translated into expenditures through assignment of cost per unit activity on the basis of 2001 Medicare reimbursement rates [16]. Although nearly 30% of our patients are uninsured and our usual collection rate is 40%, for analysis purposes, we assumed that all patients had Medicare insurance, that there was complete billing for all health care use, and that the collection rate was 100%. Expenditures were broken down by cost component, as shown in table 1.

Hospitalization expenditures were determined on the basis of Medicare reimbursement rates for diagnostic related group codes for each admission [17]. The hospital-associated expenditures included all technical expenditures associated with the hospital stay, such as inpatient medications, radiological studies, procedures, and laboratory studies, but did not include physicians' professional fees incurred during the hospital stay; both inpatient and outpatient physician professional fees were included in clinic/physician expenditures.

Data on the use of outpatient clinical services was obtained by a data warehouse query of services rendered using the IDX database system. This system captures all UAB service activity related to outpatient professional and technical fees, as well as use of all outpatient clinics, across the University Health System (including all subspecialty consultation and mental health visits), except for fees associated with emergency department visits that do not result in a hospitalization. Outpatient clinic use, which included level of clinic visits, delivery of outpatient medication services (such as delivery of infusions, injections, and chemotherapy), and laboratory use, was converted into expenditures on the basis of 2001 Medicare reimbursement rates

using current procedural terminology codes [18]. Substance abuse treatment is provided through a federally funded grant and was not captured in our outpatient clinic visits. Sensitivity analyses were conducted to assess the potential impact of the inclusion of substance abuse treatment, missed emergency room visits, and missed visits at other facilities on outcomes.

Medication expenditures were based on use data as recorded in the outpatient medical record. At each patient visit, the clinic health care provider recorded all changes to the patient medication list, including date of initiation of new medications, date of discontinuation of previous medications, and dosages. The changes included all medications prescribed by that provider or by any other provider as reported by the patient. Medication, dosage, and start and stop dates were entered into the clinical database within 24 h after each patient visit. Outpatient medication infusion and injection expenditures were included in the physician/clinic expenditures, not in the medication expenditures. Medication expenditures were assigned on the basis of the 2001 average wholesale price (AWP) for each medication recorded in the clinic database, incorporating duration of therapy as calculated through medication start and stop dates [19]. Although it was recognized that most medication payment programs often received substantial discounts, the high degree of variability in discounts between programs (and even within drug classes) made it impossible to use a consistent, meaningful discounted price. AWP was chosen as the standard for this study, because it forms the primary basis on which discounted pricing is determined. A sensitivity analysis was conducted to assess the impact of the decision to use AWP on the reported findings.

Expenditure data were aggregated into two 6-month intervals. Patients were categorized by baseline $CD4^+$ cell count into 4 strata: <50 cells/μL, 50–199 cells/μL, 200–349 cells/μL, and ≥350 cells/μL. Improvement status was defined by whether a patient's $CD4^+$ cell count category at 6 months had changed relative to the baseline category. Patients were considered to have experienced improvement if their 6-month $CD4^+$ cell count moved them into a higher $CD4^+$ cell count stratum, and their condition was considered to have worsened if they moved to a lower $CD4^+$ cell count stratum. Patients whose $CD4^+$ stratum did not change were considered to be the same, including those patients whose $CD4^+$ cell counts remained in the highest or lowest $CD4^+$ cell count group. Patients were then stratified by $CD4^+$ improvement status, and annualized expenditures were determined for each group. Annual costs represented the sum incurred during both 6-month intervals.

To correct for the nonnormal distribution of the annual cost data, we transformed the data by taking the natural log of the annual costs. All analyses were conducted using these transformed data, but results are presented using the actual costs. Analysis of variance was used to assess for overall significance of differences in expenditures between $CD4^+$ cell count categories, and Duncan's multiple range test was used to control for the analysis of variance pair-wise comparisons at the .05 level. Statistical analyses were performed using SAS software, version 8.2 (SAS Institute).

RESULTS

Of the 1041 patients seen between 1 March 2000 (±90 days) and 1 March 2001, 635 met the inclusion criteria; 309 patients did not have a baseline $CD4^+$ cell count within the specified time window, and 97 patients did not have a follow-up visit or hospitalization. The baseline demographic characteristics of this cohort are listed in table 2. These patients were predominantly white men who had sex with men, and most of the patients had good virologic responses to HAART (median viral load, 2.4 $\log_{10}$ copies/mL). More than 50% of the patients had

Table 2. Baseline characteristics of the 635 patients from the University of Alabama at Birmingham HIV outpatient clinic included in the study cohort.

Characteristic	Patients (n = 635)
Demographic characteristic	
Age, median years (range)	35 (18–66)
Male sex	491 (77.3)
White race	376 (59.2)
Behavioral characteristic	
Men who have sex with men	394 (62.0)
Injection drug use	65 (10.2)
Clinical characteristic	
$CD4^+$ cell count at baseline, median cells/μL (range)	367 (2–2671)
$CD4^+$ cell count strata	
<50 cells/mL	62 (9.8)
50–199 cells/μL	99 (15.6)
200–249 cells/μL	143 (22.5)
≥350 cells/μL	331 (52.1)
$CD4^+$ cell count pre-HAART, median nadir cells/μL[a]	144
Viral load at baseline, median $\log_{10}$ copies/mL (range)	2.4 (<1.3–6.0)
Receiving HAART[b]	510 (80.3)
History of opportunistic infection	171 (26.9)
Hyperlipidemia	325 (51.2)
Diabetes mellitus	65 (10.2)
Coronary artery disease	6 (1.0)
Insurance status	
Public	197 (31.0)
Private	344 (54.2)
None	94 (14.8)

NOTE. Data are no. (%) of patients, unless otherwise indicated.

[a] n = 570.

[b] HAART was defined as any combination of ≥3 antiretroviral medications.

$CD4^+$ cell counts ≥350 cells/μL. Twenty patients died during the analysis period; the median duration of follow-up for these patients was 7 months.

The annual expenditure data were aggregated into two 6-month intervals, with the mean 1-year totals for each $CD4^+$ cell count category listed in table 3. The distribution of the total expenditures differed significantly across $CD4^+$ cell count categories; patients with $CD4^+$ cell counts <50 cells/μL generated $36,532 per patient per year in expenditures, whereas patients with $CD4^+$ cell counts ≥350 cells/μL generated expenditures of $13,885 per patient per year ($P < .0001$). In contrast, viral load strata were less discriminatory, with strata of <50 copies/mL, 50–4999 copies/mL, 5000–99,999 copies/mL, and >100,000 copies/mL resulting in expenditures of $17,142, $17,176, $18,295, and $28,825 per patient per year, respectively.

The increased expenditures for patients with low $CD4^+$ cell counts were predominantly attributable to increased nonantiretroviral medication and hospitalization expenditures (table 3; figure 1*A* and 1*B*), although all expenditures were significantly higher for patients with $CD4^+$ cell counts <50 cells/μL than they were for patients with $CD4^+$ cell counts ≥350 cells/μL ($P \leq .0006$). Compared with patients with $CD4^+$ cell counts ≥350 cells/μL, patients with $CD4^+$ cell counts <50 cells/μL had hospitalization expenditures that were almost 6-fold greater and nonantiretroviral medication expenditures that were almost 8-fold greater. Fifty-one percent of nonantiretroviral medication costs for patients with $CD4^+$ cell counts of <50 cells/μL were due to antimicrobials, compared with only 17% for patients with $CD4^+$ cell counts ≥350 cells/μL. These expenditures were distributed evenly over the population of patients with $CD4^+$ cell counts <50 cells/μL and were not unduly influenced by outliers. Because antiretroviral medication costs remained relatively constant across $CD4^+$ cell count strata ($9407–$11,935 per patient per year), the proportion of overall expenditures attributable to use of antiretroviral therapy more than doubled for patients with $CD4^+$ cell counts ≥350 cells/μL (68%), compared with patients with $CD4^+$ cell counts <50 cells/μL (30%). Two percent or less of all expenditures was due to physician/clinic fees, with an average annual expenditure of <$400 per patient per year. This figure assumed that all patients had Medicare health insurance and that the collection rate per physician/clinic encounter was 100%.

To assess the impact of a decrease in immunologic status during the study period, expenditures were stratified by the change in each patient's $CD4^+$ cell count status between baseline and 6 months later (figure 1*B*). A decrease in $CD4^+$ cell count category was always associated with increased expenditures, but this increase was statistically significant only for patients whose baseline $CD4^+$ cell count was in the 50–199 cells/μL category ($P = .003$). The differences in expenditures for these patients are shown in figure 1*B*, in which patients with a baseline $CD4^+$ cell count between 50–199 cells/μL were stratified by cost component and improvement status. In a manner similar to that seen with total expenditures, the increased expenditures associated with a decline in $CD4^+$ cell count were predominantly attributable to nonantiretroviral medications ($P = .03$) and hospitalizations ($P = .05$). Expenditures for other cost components were not significantly different.

We conducted a similar analysis of data from 1 March 1999 through 1 March 2000 (data not shown) and found very similar results for the mean annual expenditures, $CD4^+$ cell count expenditure distribution, and contribution of expenditure category to overall expenditures. Because the data from 2000–2001 were more recent, we elected to present only those results. However, this does show that our results were consistent over a 2-year period.

Sensitivity analyses demonstrated little impact on the overall findings when adjustments were made for missing data regarding emergency room visits, substance abuse/mental health visits, visits at other health care facilities, or the use of full AWP in our study (table 4). Approximately 25% of our patients have substance abuse/mental health problems that warrant outpatient visits for therapy. If liberal adjustments are made in our outpatient use data to adjust for the missing data regarding emergency room visits, visits to other facilities, and substance abuse/mental health visits such that the total outpatient costs

Table 3. Mean annual expenditure per patient by cost component and $CD4^+$ cell count category for 635 patients from the University of Alabama at Birmingham HIV outpatient clinic.

		Cost per patient per year (% of total cost), by cost category					
$CD4^+$ cell count category	No. of patients	Total cost	Antiretroviral medication	Nonantiretroviral medication	Hospital costs	Other outpatient costs[a]	Physician/clinic costs
<50 cells/μL	62	$36,532 (100)	$10,855 (30)	$14,882 (41)	$8353 (23)	$1909 (5)	$533 (1)
50–199 cells/μL	99	$23,864 (100)	$11,862 (50)	$6685 (28)	$3369 (14)	$1416 (6)	$532 (2)
200–349 cells/μL	143	$18,274 (100)	$11,935 (65)	$3452 (19)	$1186 (7)	$1365 (7)	$336 (2)
≥350 cells/μL	331	$13,885 (100)	$9407 (68)	$1855 (13)	$1408 (10)	$930 (7)	$285 (2)
All	635	$18,640 (100)	$10,500 (56)	$4240 (23)	$2342 (13)	$1199 (6)	$359 (2)

[a] Other outpatient costs include outpatient radiological examinations, laboratory tests, procedures, and home health care.

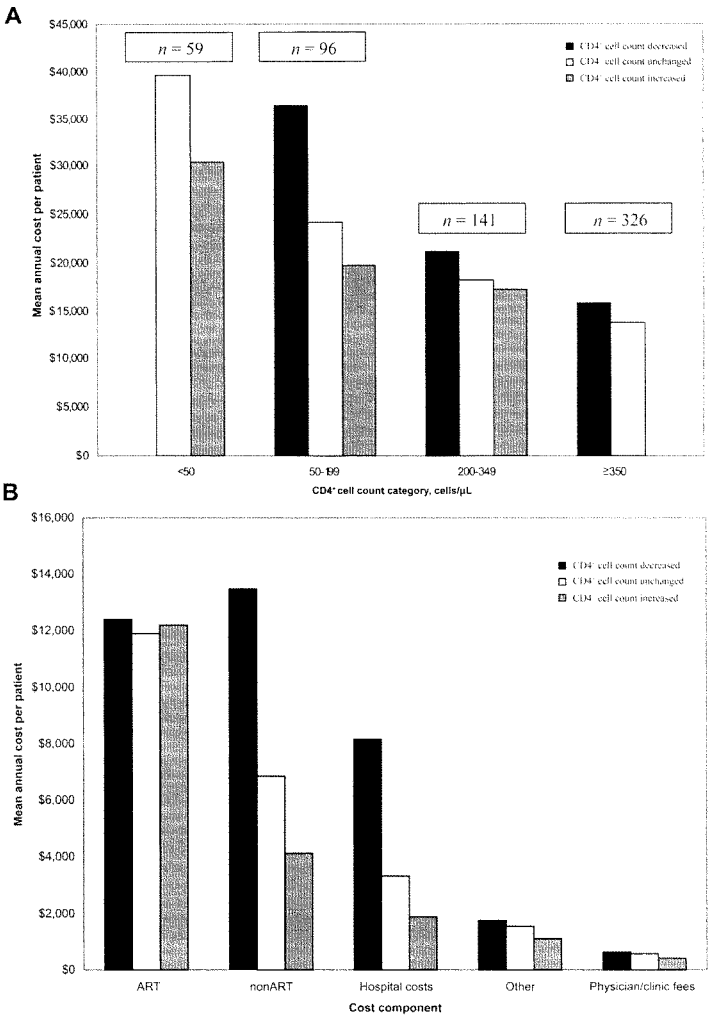


Figure 1. *A*, Assessment of changes in annual expenditures for patients whose CD4+ cell count status increased ($n = 386$), decreased ($n = 102$), or remained unchanged ($n = 134$) between baseline (1 March 2000) and 6 months (1 September 2000). A decrease in CD4+ cell count category was associated with a significant increase ($P = .003$) in annual cost among patients initially assigned to the group of patients with CD4+ cell counts of 50–199 cells/μL. The cost differences in other CD4+ cell count categories were not significantly different ($P > .2$). *B*, Assessment of the source of expenditures for patients initially assigned to the CD4+ cell count 50–199 cells/μL group whose CD4+ cell count category increased , decreased, or stayed the same between baseline and 6 months. Nonantiretroviral medication ($P = .03$) and hospital costs ($P = .05$) for patients with a decrease in CD4+ cell count category were significantly increased, compared with costs for patients with an increase in CD4+ cell count category. Differences for other cost components were not significantly significant. ART, antiretroviral therapy.

Table 4. Sensitivity analyses performed to assess impact of lower medication average wholesale pricing (AWP) and accounting for the costs of emergency room (ER) visits, substance abuse/mental health care costs, and the costs of unaccounted visits at other facilities.

Analysis	Cost per patient per year (% of total cost), by cost component			
	Medication costs	Hospital costs	Outpatient/other costs	Total costs
Initial	$14,740 (79.1)	$2342 (12.6)	$1558 (8.4)	$18,640 (100)
Incorporating AWP discounted 25%	$11,055 (73.9)	$2342 (15.7)	$1558 (10.4)	$14,955 (100)
Incorporating ER visits[a]	$14,740 (75.9)	$2342 (12.1)	$2337 (12.0)	$19,419 (100)
Incorporating ER visits, substance abuse /mental health care costs, and unaccounted visits[b]	$14,740 (73.0)	$2342 (11.6)	$3116 (15.4)	$20,198 (100)
Incorporating AWP discounted 25%, ER visits, and substance abuse/mental health care costs[c]	$11,055 (70.3)	$2342 (14.9)	$2337 (14.9)	$15,734 (100)
Combination of AWP discounted 25%, ER visits, substance abuse/mental health care costs, and unaccounted visits[b]	$11,055 (66.9)	$2342 (14.2)	$3116 (18.9)	$16,513 (100)

NOTE. The costs of ER visits, substance abuse/mental health care costs, and the costs of unaccounted visits at other facilities were each evaluated at 25%–50% of total outpatient costs.

[a] Cost of emergency room visits was evaluated at 25%–50% of total outpatient costs.

[b] Cost was evaluated at 100% of total outpatient costs.

[c] Cost was evaluated at 50% of total outpatient costs.

were doubled (from ~$1300 to ~$2600 per patient per year), the impact on our overall findings would be minimal. Medication costs would account for 73% (compared with 79%) of total costs, and HIV provider reimbursement would not increase, because these services are provided elsewhere. To explore the impact of discounted AWP pricing on our study findings, we reanalyzed our findings using a discount of 25% below AWP, a common discount for federal programs, such as the AIDS Drug Assistance Program (ADAP). With this adjustment, overall annual medication costs decreased from $14,740 to $11,055 per patient. Similarly, the overall expenditures decreased from $18,640 to $14,955 per patient per year. However, even in this scenario, medications still comprised 74% of overall expenditures, compared with 79% as determined in our primary analysis using full AWP. Using both a discount of 25% below AWP and a doubling of outpatient expenditures to account for missing visits, medications still comprise 67% of total health care expenditures.

DISCUSSION

In this study, we determined per patient expenditures of care by directly measuring health system and medication use in a population of patients receiving primary HIV care at an academic medical center clinic in the southeastern United States. Our findings demonstrate a dramatic association between annual per patient expenditures and $CD4^+$ cell counts, with patients in the lowest $CD4^+$ category expending 2.6 times more health care dollars per year than patients in the highest $CD4^+$ cell count category. The single most expensive cost component was medications, accounting for 71%–84% of the overall health care costs, depending on stage of disease. Antiretroviral therapy represented 56% of the overall costs; however, the improvement in clinical status associated with successful antiretroviral therapy, as demonstrated by increases in $CD4^+$ cell count, led to a reduction in health care expenditures in other areas. In particular, the sickest patients ($CD4^+$ cell count, <50 cells/μL) require 8-fold more nonantiretroviral medication expenditures and 6-fold more hospitalization expenditures than do the healthiest patients ($CD4^+$ cell count, $\geq$350 cells/μL). The most striking finding in this study, however, was the low expenditures for health care services provided by HIV physicians and clinics. Taken together, these findings demonstrate the relative cost of care in a fashion that informs policy makers, payers, and health care administrators.

To quantitate the reduction in expenditures associated with an increase in $CD4^+$ cell count, we assessed the impact of changes in $CD4^+$ cell count strata on annual expenditures during the year-long period of observation. Compared with patients who remained in the same $CD4^+$ cell count stratum, patients who moved to a higher stratum during the year had lower annual expenditures, whereas patients who moved to a lower stratum experienced higher expenditures. Because antiretroviral drug effects principally drive improvements in $CD4^+$ cell counts, these findings further demonstrate the clinical and economic benefit of antiretroviral therapy among patients for whom therapy is currently recommended [20, 21]. Because these data do not account for indirect costs, such as lost wages for patients and caregivers, we speculate that the true economic benefit of increased $CD4^+$ cell count status would likely be substantially greater. These data strongly validate the activity of federal programs, such as ADAP, in providing antiretroviral medications to patients who do not have prescription drug

insurance coverage. Yet, ADAP programs in many states continue to experience budget shortfalls, and many patients are in jeopardy of not having access to needed medications [22, 23].

Despite the value of antiretroviral medications in increasing $CD4^+$ cell counts and thereby decreasing costs, our data also highlight the large discrepancy between expenditures for medications and expenditures for other health care services. Most striking was the paucity of expenditures for clinic and physician services, representing ≤2% of all expenditures regardless of $CD4^+$ cell count (range, $285–$533 per patient per year). This amount includes physician fees for inpatient as well as outpatient services, making the finding even more striking. As patient outcomes have improved, owing in large part to the proper use of antiretroviral therapy, the number of inpatients has declined, and the contribution of inpatient physician reimbursement is only a fraction of physician reimbursement. Indeed, the inpatient physician component was mostly concentrated among patients with $CD4^+$ cell count <50 cell/mL and contributed little to the overall expenditures.

We utilized AWP to assign costs to medications. Because ADAP and most third-party payers receive substantial discounts below AWP to purchase medications, our findings likely overestimate the actual contribution of medication expenditures to overall costs. We chose AWP for the final analysis because of the high degree of variability in the AWP discount, which varies widely from state to state and program to program. However, even when such discounts are factored in, our conclusions do not change. For example, in our sensitivity analysis, discounting the AWP by 25% (a common discount for federal programs such as ADAP) reduced overall expenditures, but medications still comprised 74% of overall costs. The sensitivity analyses addressed several other limitations of our study, including the absence of data on emergency room visits, potential missed visits outside of the UAB health system, and substance abuse treatment visits. Indeed, when adjustments are made for these missing data elements, the overall findings of our study do not change substantially, indicating that our results are robust.

Finally, the findings in our study were derived from actual health care use activities and medication records at our clinic and hospital. The relative proportion of medication expenditures and total overall expenditures is remarkably similar to that found in previous studies conducted in the HAART era, which used estimates of health care use or models of expenditures, suggesting that our findings are likely to be generalizable [6, 8, 10, 13, 14].

In summary, the care of patients with HIV infection in the United States is associated with substantial expenditures that are driven predominantly by medication costs and are directly related to stage of disease, as determined by $CD4^+$ cell count status. Owing to the impact of treatment on improving disease status, these expenditures are, paradoxically, both decreased by and driven by the use of antiretroviral medications. The degree of expenditures generated by clinic and physician fees is quite meager and is inadequate to cover the cost of care provision at most HIV clinics in the United States, the majority of which are subsidized by federal and state dollars. The direct measurement of annual expenditures associated with delivery of HIV care has important implications for the continued support of these HIV programs and for the development of future health care policy in the United States.

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EDITORIAL COMMENTARY

Penalizing Success: Is Comprehensive HIV Care Sustainable?

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(See the article by Chen et al. on pages XXX–XX)

At the outset of the AIDS epidemic in the early 1980s, the initial contact of many patients with the health care system was their hospitalization for life-threatening opportunistic infections. Death rates were unacceptably high, but so were the inordinate expenses for costly and recurrent inpatient stays, the need for frequently invasive diagnostic procedures, and polypharmacy with expensive antimicrobial agents [1]. The advent of HAART led to marked reductions in morbidity, mortality, and inpatient hospitalizations for people living with HIV infection, but as people have lived longer, new costs for optimal care have emerged [2, 3]. HIV care has increasingly become subspecialized, necessitating a cadre of well-trained providers who understand the optimal combinations of the >20 antiretrovirals now available for treatment, their side effects, and the complex interactions with the many other medications patients with HIV infection receive, ranging from cholesterol-lowering medications to antidepressants. HIV care providers also need to be specialists in strategies to optimize medication adherence and deal with common concomitant issues like substance abuse, and they need to be trained in techniques to decrease sexual risk taking [4].

The study by Chen et al. [5] of costs at the University of Alabama HIV clinic (published in this issue of *Clinical Infectious Diseases*) demonstrates some good news and some worrisome findings about the current state of HIV clinical care one-quarter of a century after the initial recognition of the epidemic. Chen and colleagues were able to clearly show that expert clinical management leading to improvements in patients' $CD4^+$ cell counts is cost effective, with the annual costs of care for patients with $CD4^+$ cell counts <200 cells/mL being $36,533 per patient and the annual costs of care for patients with $CD4^+$ cell counts >350 cells/mL being only $13,885 per patient. Both of these figures are remarkable, compared with the "bad old days," when annualized costs of HIV care routinely exceeded $100,000 per patient [1]. For the sicker patients, inpatient hospitalization costs were the major source of expenses, whereas the average annual cost of HAART (~$10,500) for patients with higher $CD4^+$ cell counts made up the bulk of their annual health care expenses. Because patents will expire for several antiretroviral drugs in the next few years (starting with zidovudine in the next year), the costs of many first-line regimens might be expected to decrease in the coming years, further accentuating the revolution in clinical care and attendant costs associated with HAART. On the other hand, as HIV-infected people live longer, some will need expensive new agents that target new steps in the viral life cycle, such as entry and integration, and common comorbid conditions may become clinically manifest (e.g., chronic liver disease and dyslipidemias with attendant atherogenic complications), each new issue necessitating increased costs to optimize patient quality of life and survival. So, the good news is that patient outcomes have improved along with a decrease in many patient care costs, but the future of continued success is not clear, given new expenses associated with optimizing the management of HIV infection as a complex, chronic disease.

Another concern raised by Chen et al. [5] was the inadequate support for the clinical care of HIV-infected patients, with only $359 per year going to physician costs (~2% of the aggregate expenses for providing care to the 635 patients they followed up in 2000–2001). Over the past 2 decades, the paradigms for the ideal manner in which HIV care should be provided have been in flux, with some at the outset of the epidemic suggesting that all primary care medical providers should be able to manage HIV-infected patients, to decrease the stigma that has haunted the infection since its initial description in men who had sex with men and injection drug users. The cadre of the first front-line HIV care providers included generalists whose practices involved large numbers of men who had sex with men, physicians involved

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with addiction medicine, and academic infectious disease specialists, hematologists/oncologists, and immunologists. However, with the advent of HAART (entailing the need to know how to combine >20 antiretroviral drugs) and the emergent complications of long-term infection, partial immunosuppression, and long-term medication exposure, evidence suggests that patient outcomes are best if care is provided by physicians who are highly experienced in HIV care and/or have additional training beyond a grounding in primary care.

The increased specialization of HIV care has led to the creation several national and international organizations of HIV-focused health care providers. In recognition of the fact that there may be many paths to becoming an HIV specialist, the HIV Medicine Association (which operates under the aegis of the Infectious Disease Society of America) includes members with a diverse array of training experiences, including pediatricians, obstetricians/gynecologists, and family medicine providers, as well as infectious disease and other specialists [6]. The American Academy of HIV Medicine also serves a broad array of HIV care providers and offers a credentialing examination developed by leaders in the organization, enabling physicians and other health care providers to demonstrate their competence in HIV care [7]. The HIV Medicine Association has felt that approaching credentialing through the more established route (i.e., having the American Board of Medical Specialties approve the process for the development of an approved certification in HIV medicine by developing an examination overseen by an independent body) made the most sense.

Internationally, organizations like the International AIDS Society have helped to support the creation of national professional organizations of HIV specialists that are grappling with similar issues regarding training and credentialing [8]. Although the goal of the ambitious "3 by 5" initiative of the Joint United Nations Program on AIDS—to administer antiretroviral therapy to 3,000,000 people in the developing world by the end of 2005—was not met, there are now >1,000,000 people in low- and moderate-income countries being treated with HAART [9]. The prospects for further scaling up access to antiretroviral therapy and monitoring during the next few years are great, given the commitments of international donors through the Global Fund, as well as national initiatives, like the US government's Presidential Emergency Program for AIDS Relief. The increased availability of new resources for AIDS care creates an urgent necessity for enhancing professional training opportunities across the globe. There is also a pressing need to develop tools for the ongoing assessment of workforce capability and quality-of-care that address the challenges created by the diagnosis and management of increasing numbers of people living with a complex, chronic infectious disease that requires a panoply of antiretroviral and other medications.

The development of HIV/AIDS care as a medical subspecialty has many ramifications, including the need to support the training and career development of professionals who make a commitment to this vital clinical domain. Ironically, in the current era, the urgent need to support HIV care in the United States is in conflict with the tendency towards fiscal austerity in the health care sector, as one way to address a spiraling federal budget in the wake of the "war on terrorism" and natural disasters. There is a paradox developing that is well-illustrated by the interesting findings of the study by Chen et al. [5], that HIV-infected patients in the United States are faring better in the current care model then they fared earlier in this epidemic, and their health care is costing less and less. However, the actual amount of money being paid to their specialized HIV care providers is very small and is not commensurate with the increasing needs for specialized training. Moreover, because of the increasing US federal debt burden, the US Congress and the Bush administration are trying to squeeze vital programs, such at the Ryan-White Act and the Medicaid program, which are the main sources of funding for the complex, multidisciplinary care that HIV-infected patients need. Cutting physician reimbursement seems like an easy target [10].

It is important for the readership of *Clinical Infectious Diseases* to be as informed as possible about the latest political developments that could have an impact on HIV care. The reimbursement situation in many other industrialized nations is similar to that in the United States, in that governmental programs are increasingly scrutinizing budgets and attempting to hold down costs, with the possibility of compromising quality by not supporting the work force. This conundrum may become worse in resource-constrained environments, where the costs of generic antiretroviral medications and the necessary clinical monitoring will exceed the average annual per capita expenditures on health care. This may make policy makers think that one area in which they can control costs will be to limit training, provider reimbursement, and ongoing quality-of-care surveillance. This would be penny-wise and pound-foolish. So much has been accomplished in the past quarter of a century that guarantees opportunities for a fine life for HIV-infected people. It would be a shame to have the boulder roll back down the hill in a Sisyphean manner because of the lack of resolve by governmental authorities and international aid agencies to adequately support the increasingly sophisticated health care needs of a highly vulnerable patient population.

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April 14, 1997

Honorable Donna E. Shalala
Department of Health and Human Services
200 Independence Avenue, S.W.
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Dear Secretary Shalala,

As you know, the Ryan White CARE Amendments of 1996 signed into law last year required that "a good faith effort be made to notify a spouse of a known HIV-infected patient" by a State as a condition of receiving grants under Part B of Title XXVI of the Public Health Service Act.

I would like to know precisely what passes as a "good faith effort", when will this policy go into effect, which States have already enacted spousal notification and who is responsible for notification.

Thank you for your attention to this matter. I look forward to your prompt reply.

Sincerely,

Tom A. Coburn, MD
Member of Congress

TAC: rf

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Congress of the United States
House of Representatives
Washington, DC 20515-3602

July 22, 1997

Honorable Donna E. Shalala
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Shalala,

I wrote to you on April 14, 1997 regarding the status of the federal spousal notification requirements for HIV infection and have not yet received a response.

As you know, the Ryan White CARE Amendments of 1996 signed into law last year required that "a good faith effort be made to notify a spouse of a known HIV-infected patient" by a State as a condition of receiving grants under Part B of Title XXVI of the Public Health Service Act.

I would like to know precisely what passes as a "good faith effort", when will this policy go into effect, which States have already enacted spousal notification and who is responsible for notification.

Thank you for your prompt attention to this matter. I look forward to a timely reply.

Sincerely,

Tom A. Coburn, MD
Member of Congress

TAC: rf

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U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

December 19, 1997

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

Congressman Coburn wrote to you on April 14, 1997, regarding the status of the federal notification requirements for spouses of HIV-infected individuals. In his letter, Congressman Coburn asked you several questions, including what passes as a "good faith effort," when this policy will go into effect, which States already have enacted spousal notification requirements and who is responsible for notification. On April 21, 1997, you sent a note to Congressman Coburn confirming that you had received his letter and that you would be responding "as quickly as possible." However, no response has yet been received. A subsequent letter from Congressman Coburn requesting the same information was sent to your attention on July 22, 1997. This time there was no reply. Therefore, we are writing to you to follow-up on Congressman Coburn's previous letters and to request certain information and documents.

As you know, on May 20, 1996, President Clinton signed Public Law 104-146, the Ryan White CARE Act Amendments of 1996. Under this legislation, in order to be eligible to receive federal funds, States are required to take "administrative or legislative action to require that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to the human immunodeficiency virus and should seek testing."

We are very troubled by the Department's lack of attention and timely reply to Congressman Coburn's initial request which was made more than eight months ago. Additionally, the Committee is interested to learn about the manner in which the "good faith effort" requirement of this law is being implemented by the States and your Department. Accordingly, pursuant to Rules X and XI of the U.S. House of Representatives, please provide the following information and documents by January 7, 1998:

1. Please explain why the Department has failed to respond in a timely manner to Congressman Coburn's requests.

2. Please provide all records related to the consideration, review and development of a response to Congressman Coburn's requests.

3. Please provide all records relating to the Department's development of the criteria of practices that constitute a "good faith effort."

   a) Please explain in detail what constitutes a "good faith effort."

   b) Please explain in detail what constitutes a "good faith effort" of notification in situations where a State has a reasonable belief that an HIV-infected person does not intend to notify his or her spouse or former spouse of possible exposure to HIV. More specifically, in these situations, who will be responsible for spousal notification?

4. Please provide copies of all communications, including but not limited to letters, memoranda, notes and e-mails, between the Department and the States with respect to the "good faith effort" requirement.

5. In a March 1997 Center for Disease Control newsletter article entitled "*CDC, HRSA Work to Implement CARE Act Provision*," it states that, in December 1996, CDC "mailed to each State information packets that included a certification form for the appropriate State health official to sign and return to CDC no later than February 1," and "States were asked to include a brief summary of the administrative or legislative actions they have taken, along with plans for additional actions in the future, for requiring or ensuring that a 'good faith effort' is made to notify spouses of known HIV-infected individuals of their exposure and to refer them for testing." According to the article, a State's summary would be reviewed by "CDC and the Health Resources and Services Administration (HRSA) on a state-by-state basis to determine compliance with the statute and/or the need for technical or other assistance in gaining compliance." Accordingly, please provide the following information:

   a) a copy of each State's completed certification form and "summary" provided to CDC and HRSA and the date it was originally submitted;

   b) whether each State's summary was determined to be in compliance with the statute as submitted and the date the Department made that determination; and

c) if a State's proposal was found to be not in compliance as submitted, please explain in detail the deficiencies. If a State took subsequent steps to gain approval, please explain in detail the steps taken. Please provide a copy of all correspondence (letters, memoranda, notes and e-mail) between the Department and individual States related to the States' efforts to gain compliance.

For purposes of responding to this request, the term "records," "relating," and "relate" should be interpreted in accordance with the Attachment to this letter.

If you have any questions, please contact Mr. Mark Paoletta, Chief Counsel for oversight and investigations, at (202) 225-2927. We appreciate your cooperation in this matter.

Sincerely,

Tom Bliley
Chairman

Tom A. Coburn
Member of Congress

cc: The Honorable John D. Dingell, Ranking Member
The Honorable Joe Barton, Chairman
Subcommittee on Oversight and Investigations
The Honorable Ron Klink, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

For the purposes of this request, the word "records" shall include but shall not be limited to any and all originals and identical copies of any item whether written, typed, printed, recorded, transcribed, punched, taped, filmed, graphically portrayed, video or audio taped, however produced or reproduced, and includes but is not limited to any writing, reproduction, transcription, photograph, or video or audio recording, produced or stored in any fashion, including any and all computer entries, memoranda, diaries, telephone logs, telephone message slips, tapes, notes, talking points, letters, journal entries, reports, studies, drawings, calendars, manuals, press releases, opinions, documents, analyses, messages, summaries, bulletins, e-mail, disks, briefing materials and notes, cover sheets or routing cover sheets or any other machine readable material of any sort whether prepared by current or former employees, agents, consultants or by any non-employee without limitation. "Records" shall also include redacted and unredacted versions of the same record. For purposes of this request, the terms "relating" or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN 26 1998

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515-3602

Dear Dr. Coburn:

This is in response to your letters regarding implementation of the spousal notification provisions of the Ryan White CARE Act Amendments of 1996. The Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) jointly coordinated the implementation of these provisions that went into effect April 1, 1997. I apologize for the lateness of this response.

In response to your inquiries, enclosed is a summary of relevant CDC policies and activities entitled *Additional Information Regarding Implementation of Spousal Notification Provisions of the Ryan White Care Act Amendments of 1996*. Also enclosed is a *Guide to Public Health Practice: HIV Partner Notification Strategies* (Association of State and Territorial Health Officials, et al., 1988). Additional materials requested in your December 19, 1997 letter cosigned by Congressman Bliley will be forwarded shortly. I hope this information is helpful.

Sincerely,

Donna E. Shalala

Enclosures

ADDITIONAL INFORMATION REGARDING IMPLEMENTATION OF SPOUSAL NOTIFICATION PROVISIONS OF THE RYAN WHITE CARE ACT AMENDMENTS OF 1996

PREPARED BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) began working on implementation of the spousal notification provisions of the Ryan White Care Act Amendments of 1996 shortly after Congress reauthorized the Act. In the fall of 1996, CDC and HRSA began soliciting input from a broad group of State representatives and constituents. This part of the collaborative process was completed by February 1, 1997. CDC was also responsible for obtaining, by February 1, States certifications of their administrative or legislative plans to require a good-faith effort to ensure that spouses of known HIV-infected individuals are notified of their possible exposure to HIV and referred for testing. In this regard, CDC reviewed the States plans to determine compliance with the statute and need for technical assistance that States may have regarding spousal notification.

CDC and HRSA agreed that appropriate State health agency officials should have the authority to define a good-faith effort for their jurisdictions. Examples of program principles and practices that CDC believes would minimally constitute a good-faith effort regarding HIV spousal notification were developed by CDC and HRSA in consultation with health department and community representatives and were provided to the States in their certification packages. These included the following:

- For individuals reported to the State on or after April 1, 1997, as being diagnosed with AIDS (or HIV infection in States requiring HIV-infection reporting by law or regulation), if not already determined by the reporting health care provider, each such individual shall be:

  -- asked if he or she has, or has had, a spouse (defined by this law as "any individual who is the marriage partner of an HIV-infected patient or who has been the marriage partner of that patient at any time within the 10-year period prior to diagnosis of HIV infection");

  -- informed that he or she should notify his or her spouse, or former spouse(s), of the potential exposure to HIV.

- Reasonable efforts must be made to determine if each HIV-infected individual intends to notify his or her spouse of their possible exposure to HIV or agrees to have a qualified health care provider notify them. In situations where the HIV-infected individual reports that he or she intends to notify the spouse, culturally competent counseling and

educational services on the following issues should be available:

-- how to make the notification;

-- how to preserve confidentiality of both the individual and the spouse;

-- how HIV infection and transmission can be prevented;

-- how the spouse can access testing, other prevention services, and treatment.

If the HIV-infected individual is unable or unwilling to notify his or her spouse, culturally competent services should be available from the provider or the health department to do so. Unless covered by existing law, policy, or regulation, States should develop policies that address situations involving HIV-infected individuals who do not plan to notify their spouses and who refuse health department assistance. In developing these laws, policies, or regulations, States should consider guidance contained in the *Guide to Public Health Practice: HIV Partner Notification Strategies* (Association of State and Territorial Health Officials, *et al.*, 1988).

Reasonable procedures to ensure that notified spouses receive referrals for HIV testing, other prevention services, and treatment should be implemented.

Health departments that (1) document spousal notification policies and practices of public and private health care providers who report AIDS or HIV that meet State requirements or (2) establish agreements with them for this purpose need not directly contact every HIV-infected individual reported by such providers for purposes of spousal notification.

As of February 1, 1997, CDC and HRSA had determined that all 50 States were essentially in compliance with Public Law 104-146. Most States cited existing laws or regulations that they use to enable notification of sex or drug-using partners of HIV-infected persons. Sixteen States and Territories indicated they intended to introduce or change (or provided an example of) a rule, statute, or law to improve compliance with the Public Law. Fifty-one States and Territories indicated changes in administrative procedures, including changes to policy and procedures manuals, that would be conveyed to health department and contracting clinic staff. In addition, 44 States and Territories indicated they will encourage private medical providers (even though the law applies only to federally funded entities) to adopt the spousal notification guidelines within their nongovernment-supported practices. Most of these providers indicated that they would do this through periodic newsletters,

"Dear Colleague" letters, professional society membership letters, or similar communications.

Currently, all States that receive CDC funds for HIV/AIDS prevention activities are required to establish standards and implement procedures, in addition to the spousal notification requirements, for confidential, voluntary notification of sex and needle-sharing partners of HIV-infected persons. CDC considers partner notification to be a primary prevention service with the following objectives:

- To provide prevention information to persons, if not already infected, who may be at very high risk of becoming HIV infected but are unaware of or misunderstand their risks;
- To assist these individuals in obtaining other services such as HIV counseling, testing, referral, and additional HIV prevention counseling;
- To provide access to partners who are already infected to secondary HIV prevention services that can improve their health and quality of life.

CDC recommends that States provide partner notification services in both anonymous and confidential testing sites. CDC further recommends that States provide either partner notification services or the necessary training to conduct these services for physicians or hospitals who provide HIV counseling and testing.

In late 1996, CDC began a process to review and update its general guidance on HIV prevention partner notification, including additional guidance relevant to spousal notification. CDC is collaborating with State and local health departments, HRSA, the National Governors Association, and representatives of affected communities in this endeavor and plans to issue revised guidance in mid-1998.

spe .ction

GRANTEE	Date Received	Acceptable	Current Law	Rev. Protocl	Reg. Change	Training	"Jawbone"
ALABAMA	1/31/97	Y	X	X	X	X	X
ALASKA	1/29/97	Y	X	X		X	X
ARIZONA	1/30/97	Y	X	X		X	X
ARKANSAS	1/30/97	Y		X		X	X
CALIFORNIA	2/5/97	Y	X	X		X	X
COLORADO	1/29/97	Y		X		X	X
CONNECTICUT	1/31/97	Y	X	X		X	X
DELAWARE	1/28/97	Y		X	X	X	X
DISTRICT OF COLUMBIA	1/8/97	Y	X	X		X	X
FLORIDA	1/28/97	Y	X	X	X	X	X
GEORGIA	2/1/97	Y	X	X	X	X	
GUAM	1/28/97	Y		X	X	X	X
HAWAII	12/22/96	Y	X	X		X	X
IDAHO	1/19/97	Y	X	X			X
ILLINOIS	1/17/97	Y				X	X
INDIANA	2/4/97	Y	X	X		X	X
IOWA	1/31/97	Y	X	X		X	X
KANSAS	1/31/97	Y	X	X		X	X
KENTUCKY	2/1/97	Y	X	X		X	X
LOUISIANA	2/1/97	Y	X	X	X	X	X
MAINE	1/29/97	Y	X	X		X	X
MARYLAND	2/1/97	Y	X	X	X	X	
MASSACHUSETTS	1/31/97	Y	X	X		X	X
MICHIGAN	1/31/97	Y	X	X		X	X
MINNESOTA	1/29/97	Y	X	X		X	X
MISSISSIPPI	2/1/97	Y	X		X	X	
MISSOURI	1/10/97	Y	X	X		X	
MONTANA	2/1/97	Y		X		X	X
NEBRASKA	1/21/97	Y		X		X	X
NEVADA	1/24/97	Y	X			X	X
NEW HAMPSHIRE	1/31/97	Y	X	X		X	X
NEW JERSEY	1/28/97	Y			X	X	X
NEW MEXICO	2/1/97	Y		X		X	X
NEW YORK STATE	2/5/97	Y	X	X		X	X

spo. .tion

NORTH CAROLINA	2/1/97	Y	X				
NORTH DAKOTA	1/29/97	Y		X		X	X
NORTHERN MARIANA IS	2/13/97	Y		X			
OHIO DEPT	1/6/97	Y		X	X	X	X
OKLAHOMA	1/31/97	Y		X		X	X
OREGON	2/3/97	Y	X	X		X	X
PALAU	1/21/97	Y					
PENNSYLVANIA	12/14/96	Y		X		X	X
PUERTO RICO	2/5/97	Y			X	X	X
RHODE ISLAND	1/29/97	Y	X	X	X	X	X
SOUTH CAROLINA	1/21/97	Y	X	X		X	X
SOUTH DAKOTA	1/29/97	Y				X	X
TENNESSEE	2/1/97	Y		X	X	X	
TEXAS	1/30/97	Y				X	X
UTAH	1/24/97	Y			X	X	
VERMONT	12/22/97	Y				X	X
VIRGIN ISLANDS	3/18/97	Y	X			X	X
VIRGINIA	1/29/97	Y	X			X	
WASHINGTON	2/1/97	Y			X	X	X
WEST VIRGINIA	1/30/97	Y		X	X	X	X
WISCONSIN	1/24/97	Y	X	X		X	X
WYOMING	12/22/96	Y	X	X	X	X	
				[illegible]	[illegible]	[illegible]	[illegible]

Current Law: Many States and Territories cited existing laws or regulations that they use to enable notification sex or drug contacts. In only a few situations was the term "spouse" used or referenced. Presumably, more States do have laws, rules or regulations that permit such health department follow up of sexual or injection sharing drug contacts, however, the correspondence does not mention them.

Reg. Change: While no State had actually passed legislation by the February 1, 1997 deadline, 17 had indications that they had (with text example provided) that they intended to introduce or change a Rule, Statue or law to better comply with P.L. 104-146.

Rev. Protoc: 42 States/Territories indicated changes in protocols that are to be followed in funded sites and contracted health care providers.

Training: 51 States/Terriotries indicated changes in training procedures and manuals used. This includes changes to policy/procedure manuals.

"Jawbone": 45 States and Territories will encourage private medical providers to adopt the spousal notification guidelines with their non-government supported practices. Most indicated that they would use periodic newsletters, Dear Colleague letters, mailings to professional society members, etc.

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

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Congress of the United States
House of Representatives
Washington, DC 20515–3602

March 6, 1998

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Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Shalala,

Thank you for your February 2nd response to my letter regarding the status of the Federal notification requirements for spouses of HIV-infected individuals co-signed by Chairman Thomas Bliley, Jr.

As you know, the Ryan White CARE Amendments of 1996 required that "a good faith effort be made to notify a spouse of a known HIV-infected patient" by a State as a condition of receiving grants under Part B of Title XXVI of the Public Health Service Act. The information which you have provided indicates that every state has complied with this requirement.

However, I recently read in the January 25th edition of the New York Times that New York state's "existing policy prohibits caseworkers from notifying any sex partner, including spouses, without the voluntary consent of the HIV-positive person." Furthermore, it stated that "a Health Department spokesman, Fred Winters, said the spouse policy was 'under review.'" (I have enclosed the article with these passages highlighted.)

If this is indeed the case and New York state has not yet enacted a spousal notification program, how is it that the state was certified to receive Ryan White CARE grants? Furthermore, how do we know that other states which have been certified as complying are actually fulfilling this and other Federal conditions necessary to be eligible for such grants?

Thank you for your attention to this matter. I look forward to hearing from you shortly.

Sincerely yours,

Tom A. Coburn, MD
Member of Congress

cc: Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce

Enclosure

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Breaking the H.I.V. Chain

Counselors Battle the Spread of Infection — and Despair



Chang W. Lee/The New York Times

People who may have been exposed to a sexually transmitted disease are counseled in Jamaica, Queens, by workers at one of 10 city clinics.

The New York Times
New York Report
SUNDAY, JANUARY 25, 1998

By JIM YARDLEY

Yasmin Ramos delivers the knock on the door that no one wants to answer. She is a senior public health adviser for New York City, a petite woman six months' pregnant whose job includes untangling the web of sexual partners that begins with a single case of H.I.V.

Once, as she searched for a woman exposed to H.I.V., the virus that causes AIDS, Ms. Ramos unwittingly stumbled into a brothel. When she visits certain public housing projects, she raps on the door and jumps to the side, wary of gunshots. Often, she needs only to pick up the phone and call people from the clinic where she works in Jamaica, Queens.

There, in a nondescript building, more than 1,200 people a month arrive in an unceasing current. Like the homeless man who hoped to test positive for H.I.V. to qualify for welfare benefits. Or the middle-age man who tested positive but has refused to allow his two pregnant girlfriends to be notified. Or the young couple who canceled their wedding after they learned he was positive but she was not.

"I've run the gamut," said Una Byfield, one of the supervisors at the Jamaica clinic, "from anger to frustration to sadness."

Ms. Ramos and Ms. Byfield are New York City's foot soldiers in fighting the spread of H.I.V. They counsel people who test positive and seek to notify their sex partners, a process known as contact tracing or partner notification. Though contact tracing is a common public health strategy for fighting sexually transmitted disease, it is a contentious practice when applied to H.I.V., because of the stigma attached to the virus.

Even voluntary tracing, some critics fear, threatens a patient's confidentiality and privacy. But supporters say tracing offers the best way to protect the rights of people unknowingly exposed to the disease.

Inside the Jamaica clinic, Ms. Byfield and her colleagues consider their work vital to the public health, particularly as new treatments for AIDS are becoming available. H.I.V., Ms. Byfield said, "does not equal death anymore; it means living their life differently, starting today."

> Following the public health officials whose job is delivering bad news.

"My feeling is that everyone can be helped," she said. "That's what my whole life is centered around. I believe I'm helping people."

Last November, the case of an H.I.V.-positive drifter, Nushawn J. Williams, focused public attention on contact tracing after public health officials upstate and in New York City linked him to at least 16 young women infected by the disease. But just as the identity and H.I.V. status of anyone who walks into the Jamaica clinic is protected by strict confidentiality laws, so, too, has the work of contact tracers remained largely concealed from view.

Breaking with its usual policy, however, the city's Health Department recently allowed a reporter to interview employees of the Bureau of Sexually Transmitted Disease Control, including four people from the Jamaica clinic, one of 10 operated by the city. Employees could neither identify anyone infected with H.I.V. nor discuss cases except in broad detail. Initial interview sessions were monitored by supervisors.

Earlier this month, the same issues of confidentiality and privacy that cloak contact tracing erupted in a different context. The Gay Men's Health Crisis, the nation's largest AIDS service organization, reversed itself and called on New York doctors to report H.I.V.-positive people to the state as a means of better measuring the extent of the epidemic. Later, after an uproar from some other AIDS organizations, the group clarified its positions, saying it supported reporting only by coded identifiers, not by name.

At the Jamaica clinic, it is Ms. Ramos and Jeffrey King, another senior public health adviser, who handle any outside partner notification calls. Sometimes, Ms. Ramos said, the door is slammed in her face; sometimes she is invited inside for coffee.

Mr. King says he has been chased over fences by pit bulls. He has paid calls on crack addicts in Queens and, less frequently, on Wall Street traders. He gives both the same direct but deliberately vague message: You have come in contact with someone infected with a

Continued on Page 30

Continued From Page 27

sexually transmitted disease. You should come to the clinic to be tested. Only at the clinic is H.I.V. discussed.

The Toughest Part: Breaking the News

The most difficult aspect of the job is the most personal — breaking the news to someone who has tested positive. Ms. Byfield estimates she has delivered the bad news to more than 300 people in the last eight years. She prays in the mornings and she prays in the evenings. "I ask the Lord to guide me as to what to say," she said.

Mr. King guesses he has told at least 100 people. Yvan Pompilus, another supervisor, cannot remember an exact total, though the number is high. Ms. Ramos recalls each of the five people she has told, particularly the first. He was a husband whose wife had already tested negative. "She tried to get in the room," she recalled. "But we blocked it. She kept rapping. When we opened the door, she dropped to her knees and said, 'Tell me, tell me, tell me!' I couldn't stand it. It was horrible."

To better explain contact tracing, the employees told of a woman who recently came into the Jamaica clinic at the suggestion of a partner who had tested positive for gonorrhea. Indeed, a large majority of people who visit the clinic do so to be tested for a sexually transmitted disease other than H.I.V. Of the 1,200 or so clients a month, about 320 people agree to take an H.I.V. blood test, of whom only 5 or 6 test positive.

Most of the patients at the Jamaica clinic are heterosexual, and many are single mothers with limited incomes. Where five years ago clinic workers said they regularly saw intravenous drug users, today they are more likely to see a crack addict who has traded sex for drugs.

There are two ways a person can be tested, anonymously or confidentially. Anonymous testing means that no name or medical record is associated with the test. The staff said some people have identified themselves as Donald Duck or John Wayne or Rock Hudson. Some people come for anonymous tests because they do not want any record of H.I.V. on their insurance records. Most patients, however, are tested confidentially, which means their names and medical records remain secret.

In the case of the woman seeking the gonorrhea test, Ms. Ramos suggested that she also take the H.I.V. test. When she resisted, Ms. Ramos explained the confidentiality laws. Though she was concerned that her daughter and grandchildren might shun her, the woman agreed to take the test confidentially. When she returned for the results about a week later, she learned she was positive.

What unfolded during counseling sessions over two weeks was a gradual process of persuasion intended not only to refer the woman for medical help but also to learn the names of her sex partners. The Jamaica staff learned about the man who had suggested the gonorrhea test. He was an old lover who had resurfaced briefly in her life.

The woman agreed to notify him within three days of her H.I.V. status and bring him in for testing. But the man never appeared, and the staff re-interviewed the woman. Eventually, she turned over his beeper number. Ms. Byfield contacted him, and he came to the clinic within two weeks. He tested negative.

The woman also resisted disclosing the identity of her current partner. Often, the Jamaica caseworkers say, this hesitation is simply the person's fear that the partner will abandon him or her. Eventually, after several meetings, the woman acknowledged a past addiction to crack and agreed to bring in her current partner. He was tested the next day. He, too, was negative.

While the woman's case illustrates the perseverance often needed to determine a person's sexual contacts, it also reveals inevitable limitations: because both men tested negative, the source of the woman's infection has not been discovered. It could have been drug-related or another sex partner. And the woman has so far resisted treatment programs. "The last time we spoke with her, she was still in denial," Ms. Byfield said. "She would not budge. Sometimes we aren't able to solve all the problems."

When the Infected Won't Tell Spouse

Though the staff pitied this woman, there are cases that deeply frustrate them. Mr. King said he has seen occasional cases in which H.I.V.-positive patients refuse to notify their spouses. (Existing policy prohibits caseworkers from notifying any sex partner, including spouses, without the voluntary consent of the H.I.V.-positive person. A Health Department spokesman, Fred Winters, said the spouse policy was "under review.")

Ms. Byfield told of a man who repeatedly returned to the clinic for different diseases. He consistently ignored efforts at counseling until he finally contracted H.I.V., she said. Still, Ms. Byfield said the man refused to tell his partner. "And he wanted to have a baby with her," she said. "He thought if he told her, she would leave him. I felt anger toward him."

There are also cases that amaze even the staff. Mr. Pompilus recalled the homeless man who believed a positive H.I.V. test represented his best chance of collecting welfare benefits. He said he had seen four or five such cases over the years. Mr. King said he knew of cases in which an anguished spouse who tests negative will intentionally engage in unprotected sex with his or her H.I.V.-positive partner. "How can you make someone practice safe sex who wants to be positive?" Mr. King asked.

Councilman Thomas Duane said he regarded the city's disease control workers as models of professionalism. But Mr. Duane nonetheless is a critic of partner notification. He warns against the potential for unintended consequences, such as inadvertently outing homosexuals or endangering women.

"If a woman is living in a domestic violence situation, and they then tell her spouse or partner that she is positive, that places her at even greater risk," Mr. Duane said.

Mandatory Notification Is Other Side of Debate

On the other side of the debate are those who advocate a mandatory partner-notification system. But AIDS activists and city health officials say that notification must remain voluntary or people might regard the system as coercive and refuse to be tested.

"That would be the end of testing as we know it," said Steve Rubin, the bureau's deputy director. "What are we going to do if you don't tell us? We shoot you?"

The political debate seems far removed from the Jamaica clinic, where the concern is meeting the needs of the daily wave of new people. Of the four Jamaica employees interviewed, only Ms. Byfield had planned on a career in counseling. She received a master's degree in counseling education from New York University, began working for the bureau in 1980 and started counseling H.I.V. cases in the late 1980's.

The others took far less obvious routes to the clinic: Mr. Pompilus, a theater and music major at Brooklyn College, had worked in real estate; Mr. King, a saxophone player with his own quartet, stumbled into the job because he needed extra money to supplement his income.

Ms. Ramos, who started as a clerical aide a decade ago, had served in the United States Army Reserve.

Her husband is a lawyer, and his friends are often stunned when they learn about Ms. Ramos's job.

"You do what?" people ask Ms. Ramos, who is still a sergeant the Army Reserve.

All four workers described the satisfactions of the job as the moment when they are able to help people. Ms. Byfield, for example, has followed one man for 14 years. He comes into the clinic for checkups related to a disease other than H.I.V. and refuses to see anyone except her. This is why Mr. Rubin describes the job this way: "We try to make the world safe for sex."

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

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June 2, 1998

Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Shalala,

I wrote to you on March 6, 1998 regarding the compliance of states with the notification requirements for spouses of HIV-infected individuals as provided by the Ryan White CARE Act Amendments of 1996.

In my letter, I included an article from the January 25th edition of the *New York Times* which stated New York's "existing policy prohibits caseworkers from notifying any sex partner, including spouses, without the voluntary consent of the HIV-positive person." I was dismayed to read in today's *New York Times* that "New Jersey's system of notifying partners is voluntary. Spouses or other partners of infected people are not notified without the consent of the infected person." I have enclosed the complete article with this section highlighted for your reference.

If these reports are true, both New York and New Jersey have failed to comply with the federal requirements and the Department of Health and Human Services has neglected to enforce the law. I would, therefore, inquire again if this is indeed the case and both New York and New Jersey have not yet enacted spousal notification programs, how is it that these states were certified to receive Ryan White CARE grants? Furthermore, how do we know that other states which have been certified as complying are actually fulfilling this and other conditions necessary to be eligible for Federal grants?

If you have any questions, please contact me or Roland Foster of my staff at (202) 225-2701. Thank you for your cooperation with this matter. I look forward to a timely response.

Sincerely,

Tom A. Coburn, M.D.
Member of Congress

cc: Thomas J. Bliley, Jr.
Chairman, House Committee on Commerce

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The New York Times

May 29, 1998

New Jersey's H.I.V. List: Valuable, and Still Secret

By LYNDA RICHARDSON

TRENTON — Inside a small locked room at the New Jersey Department of Health, a chain-link fence soars to the ceiling, encircling two chairs, a backup computer and a towering main computer. It is called the cage.

Padlocked shut, cloaked in privacy, the tall computer holds the names and addresses of 13,205 New Jersey residents who are infected with H.I.V., the virus that causes AIDS.

While every state has long maintained lists of people who have AIDS, New Jersey in late 1991 became the state with the most AIDS cases to take the next step and establish a register of people who are not necessarily ill, but who have the virus.

New York and California, the states with the highest number of AIDS cases, are now in the middle of heated debates over the issue, a debate that often pits public health goals against worries about confidentiality.

Many debates about AIDS issues happen at a fever pitch across the country, and the positions are often divisive and entrenched. In New Jersey, the relationship between advocacy groups and the government has been less strained. But the six years New Jersey has kept a list of H.I.V. cases hold a valuable lesson for other states: there have been no breaches of confidentiality; other perils that critics warn about have not come to pass, and the benefits have been abundant.

TAKING NAMES

A special report.

Public health officials say that New Jersey offers a textbook case of the value of registers of people with the AIDS virus. State officials used the register, for example, to quickly identify older people and young women as groups that needed special prevention and medical programs.

Health officials elsewhere call the lists very useful. "We would be able to do things earlier if we had H.I.V. reporting," said Dr. Richard Sun, chief of the H.I.V.-AIDS epidemiology branch of the California Department of Health.

"AIDS reporting reflects infections that happened perhaps 10 years ago," he said, adding that it would be difficult to make plans for H.I.V. prevention and care past the year 2000 with only AIDS data, and not H.I.V. statistics also.

Even in New Jersey, H.I.V. reporting has weaknesses. Although the list provides a fuller snapshot

Continued on Page A21

Continued From Page A1

of where the virus is than the list of AIDS cases, the officials say they estimate that at least 20,000 H.I.V.-positive people have not come forward to be tested. State officials say this is because many people are not aware they may be at risk of infection, not because of fear about H.I.V. reporting. In fact, officials noted that if fear were a factor, the number of New Jerseyans going to be tested in New York and Pennsylvania, neighboring states where reporting is not mandated, would have risen. That number actually declined, according to government reports that track the states of residence.

Some advocates do say the system can lead to increased pressure, even intimidation, on clinics and counselors to get the names of sexual and needle-sharing contacts. But that criticism is not widespread.

That is in part because New Jersey has no powerhouse advocacy groups like the Gay Men's Health Crisis in New York. The AIDS service organizations are smaller and scattered throughout the state. Many groups say they are hard pressed to fully evaluate H.I.V. reporting. "There aren't very many of us," said Riki E. Jacobs, the executive director of the Hyacinth AIDS Foundation in New Brunswick, the state's largest AIDS service agency. "That makes it difficult."

Many advocates for people with AIDS are vehemently opposed to name reporting, arguing that confidentiality concerns are far too important and that codes should be used instead to further safeguard privacy. They say that name reporting will discourage a significant part of the public from being tested, and hobble efforts to effectively track H.I.V. cases.

They also worry that a list of names in a government register will be used for other purposes if punitive and ineffective H.I.V. policies are enacted. And though there is a frequent claim that confidentiality is rarely breached, these advocates say that agencies cannot control how staff members use the data.

Advocates point to a widely publicized case in Florida, in which a public health worker lost his job over a computer disk listing the names of people with AIDS that was not kept secure. The disk was mailed to two newspapers along with an anonymous letter.

These advocates contend that name reporting is not essential to monitor the epidemic, focus attempts at prevention, allocate AIDS money or link people to care. As an alternative, they say that public health officials should devote as much resources to producing a viable coded system as they have been in promoting name reporting.

Proponents of H.I.V. reporting say such criticisms are mostly theoretical, while the benefits are concrete. They say the need for reporting has become more crucial with the advent of new treatments like multiple-drug therapies, which have allowed more people to stay in good health even if they have H.I.V.

The New Jersey list, they note, has enabled the state to identify 1,308 infected mothers of newborns, greatly increasing the use of an anti-AIDS drug, AZT, to reduce the chance of infection in the newborn. Officials said an AIDS register would have identified only 24 mothers.

The list led authorities to Bridgeton, in southern New Jersey, where young women in their 20's have a higher rate of H.I.V. infection than the state's overall population. Health workers are beginning a $150,000-a-year prevention program in community centers, schools and churches.

The list also revealed that men and women in their 50's account for a growing number of H.I.V. cases, indicating that the disease will be a problem among the elderly.

The Debate

Whether to Use Codes or Names

Few experts now doubt that such benefits can result for H.I.V. reporting, much in the way that Government tracking of syphilis and tuberculosis cases has gained widespread acceptance. But officials in many states, including New York, are still locked in disagreements over how H.I.V. reporting should be done and how the information will be used.

Massachusetts in February adopted an H.I.V. reporting system that will use a code, not a person's name, in state records. "People who suffer from the disease have very good reason to fear a list of their names being kept," said Sean Fitzpatrick, a spokesman for the Massachusetts Department of Health.

"There was discrimination and stigma related to having AIDS in the 80's that was very real," Mr. Fitzpatrick explained, "and for those people who lived through that time, it is still very fresh in their memories."

In New York, the State AIDS Advisory Council, which advises the Governor and the Legislature on policy, is united on the view that some sort of reporting is needed, but is bitterly divided on what method of reporting to use. The issue may be decided in the Legislature, where a host of H.I.V.-related bills are pending, including one that would mandate name reporting and notification of partners. California is at a similar impasse.

Twenty-eight states now have H.I.V. reporting of the names of both adults and adolescents. But those states account for only a third of all AIDS cases.

Lawrence O. Gostin, a director of the Georgetown University-Johns-Hopkins University Program on Law and Public Health and a member of the Centers for Disease Control and Prevention advisory committee, said, "New York and California are the two biggest states that don't have H.I.V. reporting, and it would make a huge difference politically and from a public health perspective if they move to H.I.V. reporting."

To guide states, the Centers for Disease Control are to issue recommendations within months on how to carry out H.I.V. reporting. The agency, in its own three-year evaluation, found that coded systems are unreliable and difficult to link with individuals. And Texas reached the same conclusion, scrapped its system after four years and is moving to name-based reporting.

The List

Legal Protections And Easier Routines

Even some of the most vigilant advocates for infected people concede there have been no breaches of confidentiality of New Jersey's H.I.V. register.

"In all candor, some of the worst-case scenarios that we anticipated did not occur," said Ed Martone, executive director of the American Civil Liberties Union of New Jersey. "I have not heard of any inappropriate releasing of names, purposely or accidentally, so it seems to be working at this point."

H.I.V. reporting is far from a burning issue in New Jersey. Timothy Thompson, who tested positive for H.I.V. three years ago, said he had no idea there was such a policy. And he was recently elected to the Hudson County H.I.V.-AIDS Services Planning Council, which sets local priorities on Federal AIDS spending.

"You sign stuff because they throw it in front of you," said Mr. Thompson, 35, who was attending a recent seminar on AIDS issues in Jersey City. "You're sitting there and you don't know what's going on."

In recent years, legal protections against discrimination have eased some confidentiality concerns. But a case now before the United States Supreme Court could set new rules. The Court is weighing arguments over whether the Americans With Disabilities Act covers those who are H.I.V.-positive but show no symptoms of disease. New Jersey has another safeguard: If H.I.V. records are disclosed improperly, residents can sue under the state's confidentiality law.

New Jersey residents can take a H.I.V. test that does not involve needles. Health workers at many sites now have oral collection and testing kits, which include a lollipop-like device that is inserted between the cheek and the gum to collect saliva. It is placed in a vial and shipped off to a state laboratory. Results are returned within two weeks.

Residents have the option of learning their H.I.V. status without having their names reported, if they go to 15 state-financed H.I.V. testing and counseling sites. The 200 residents a year who choose this option are identified by a number, and the state receives only demographic information like age, sex and race.

And New Jersey's system of notifying partners is voluntary. Spouses or other partners of infected people are not notified without the consent of the infected person.

The state, though, makes clear that it wants more names for its list. "It's only common-sense health practice," said Michael Shumsky, program manager of the state's counseling and testing program. "Ultimately, we see the fruits."

The Test

How a State Tracks a Case

In a bleak neighborhood near the Port of Elizabeth, a favorite haunt of drug dealers and prostitutes, counselors at a state-sponsored testing site at Elizabeth General Medical Center stress to patients that consenting to have their names recorded is a way to link them to medical services.

"It helps them get into treatment faster," said Denise Smith, a registered nurse who is the site director. "And you can personalize it more for them."

At the Elizabeth site, on the second-floor of a renovated red-brick monastery near the hospital, 82 people in 1997 were told they were infected. Positive reports are mailed to the State Health Department in Trenton. The form ends up in a small data entry room on the fourth floor where a slate-gray door displays a prominent "Do Not Enter" sign.

Inside, three data entry operators tap such information as each patient's name, address, race and medical history into computers as soft music plays on a portable radio. The paperwork is later filed in locked cabinets in a locked room.

The information is electronically sent to the H.I.V. register in the tall

computer, around the corner and down the hall, inside the chain-link cage, which was built in 1993 as a security precautionwhen the health agency moved into a building that is also occupied by the State Human Services Department.

The towering computer is not linked to any other computer system within the building. Only three state employees can get into the cage. The data entry computers can talk to the tall computer in the cage only to find out whether an H.I.V. case is a duplicate or to enter more updated material. Every other week, a protected file of H.I.V. data is transmitted to the Centers for Disease Control, after a computer program strips any identifying information from the case report.

Federal health officials say their own evaluations have found no significant differences in trends in testing between states that adopted H.I.V. reporting and states that did not. Federal officials have also reported overall declines in the numbers of positive tests in the last several years, as the high-risk cases have already been identified.

The reporting of names has led to pressure to get even more. Last December, at a regular meeting called by the Health Department for groups that it finances as testing sites, an official at the agency stressed his goal of collecting more names, which some advocates regarded as an implicit threat that they risked losing financing if they did not comply.

Laurence E. Ganges, the service director for the Health Department's Division of AIDS Intervention and Care and the official who spoke at the December meeting, said in an interview that the state had a mission to stem the spread of the virus.

"If you're interviewing a patient and you're able to get one name, in my opinion, you can get two and if you can get two, you can get four, and if you can get four, you can get eight, and if you can get eight, you can get 16," Mr. Ganges said.

"We're not talking about catching a cold," he said. "People die from the virus. Counselors have a responsibility. They just do. If they take it as a threat, that's their business."

The Flaws

Only as Good As the Information

The H.I.V. reporting system in New Jersey is only as good as the information it gets. According to epidemiological models, at least 20,000 infected people in New Jersey have not come forward to be tested or reported to the state, health officials acknowledge.

For every single AIDS case, there are 1.5 to 2.5 other H.I.V. cases, according to estimates of H.I.V. prevalence by the Centers for Disease Control. In New Jersey, the names of 13,205 H.I.V.-positive people are listed in the state register, compared with 12,629 people with AIDS.

"I think the vast majority of people don't perceive themselves at risk," said Douglas H. Morgan, who resigned early this month as the assistant health commissioner in charge of AIDS and H.I.V. prevention and control, and now has a Federal job. "People can be infected and asymptomatic for years. Until they get sick or present illnesses, they probably aren't going to get tested."

The number of people being tested also has seen a steady decline since 1992, the first full year of H.I.V. reporting. There were 80,628 tested that year but 62,088 tested in 1997. Many factors could play a role, including the explosion of publicity that followed Magic Johnson's disclosure in November 1991 that he was H.I.V.-positive.

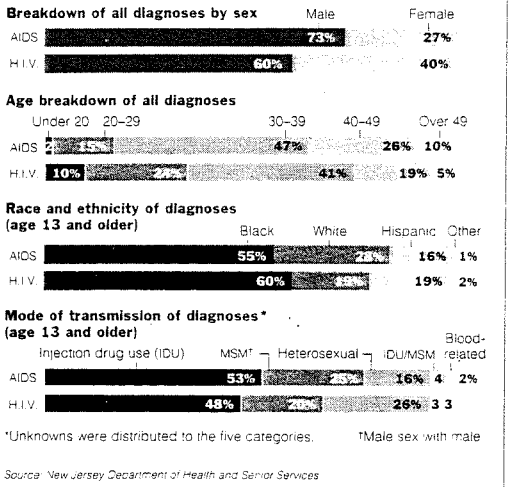
State health officials said the decline actually resulted from a shift in focus to seeking out people who are at a greater risk for H.I.V. infection.

"Everyone doesn't need to get tested," said Mr. Shumsky, the counseling and testing program manager. "People who are engaging in high-risk activities are the ones who need to be tested."

PROFILE

H.I.V. in New Jersey

Data from New Jersey's register of 13,205 cases of H.I.V. infection and 35,436 cases of full-fledged AIDS through December 1997. Totals may not add up to 100 percent because of rounding.



The New York Times

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

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June 16, 1998

Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Shalala,

I wrote to you on March 6 and then again on June 2 regarding the compliance of states with the notification requirements for spouses of HIV-infected individuals as provided by the Ryan White CARE Act Amendments of 1996. As you will recall, in my letters, I included articles from the New York Times which indicated the states of New York and New Jersey were not complying with the spousal notification requirements.

It has now come to my attention that the state of California has side stepped these requirements as well. As you can see in the attached copy of "A Brief Guide To California's HIV/AIDS Laws 1997", California law "permits (but does not require)" spousal notification. This falls considerably short of the Ryan White law which states "the Secretary of Health and Human Services shall not make a grant under part B of title XXVI of the Public Health Service Act (42 U.S.C. 300ff-21 et seq.) to any State unless such State takes administrative or legislative action to require that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to the human immunodeficiency virus and should seek testing." As a member of the conference committee, I can assure you that California's optional approach fails to meet the Congressional qualification of a "good faith effort."

I am growing increasingly concerned that the Department of Health and Human Services has neglected to enforce the law. I would, therefore, inquire for a third time how is it that these states, which failed to enact the required policies, were certified to receive Ryan White CARE grants? Furthermore, how do we know that other states which have been certified as complying are actually fulfilling this and other conditions necessary to be eligible for Federal grants?

If I do not hear from you soon with a sufficient answer I will request the relevant committees of Congress take action against the Department.

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If you have any questions, please contact me or Roland Foster of my staff at (202) 225-2701. Thank you for your cooperation with this matter. I look forward to a timely response.

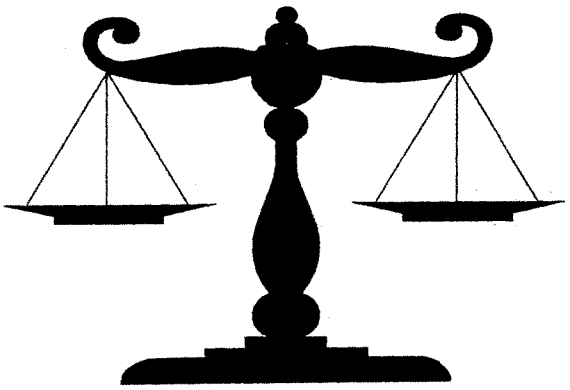
Sincerely,

Tom A. Coburn, M.D.
Member of Congress

cc: Thomas J. Bliley, Jr.
Chairman, House Committee on Commerce

Michael Bilirakis
Chairman, House Commerce Committee's
Subcommittee on Health and the Environment

A BRIEF GUIDE TO



CALIFORNIA'S HIV/AIDS LAWS

1997

Pete Wilson, Governor
State of California

Sandra R. Smoley, R.N., Secretary
Health and Welfare Agency

S. Kimberly Belshé, Director
Department of Health Services

DISCLOSURE OF TEST RESULTS

Written Authorization Requirements

Health and Safety Code Section 120980 requires that persons responsible for the care and treatment of an individual who takes an HIV test obtain written authorization prior to any disclosure of the individual's test results. The statute requires a separate written authorization for each disclosure. The written authorization must state to whom the results will be disclosed. Further, the statute provides for a civil penalty of up to $1,000 for each negligent unauthorized disclosure and $1,000 to $5,000 for each willful disclosure. A negligent or willful disclosure that results in economic, bodily, or psychological harm to the test subject is a misdemeanor punishable by imprisonment of up to one year and/or a fine of up to $10,000.

Physician Exceptions to Written Authorization Requirements

Inclusion of a person's HIV test result in that person's medical record is not considered a disclosure under Health and Safety Code Section 120980. Health and Safety Code Section 120985 permits a physician who orders an HIV test to record the results of that test in the test subject's medical record or otherwise disclose it without written authorization to the test subject's providers of health care for the purpose of diagnosis, care, or treatment of the test subject. This section defines "providers of health care" as those defined in Civil Code Section 56.05(d), except that it excludes group practice prepaid health care service plans. Recording or disclosing test results in accordance with Section 120985 does not authorize further disclosures unless otherwise permitted by law.

Partner Notification Exception to Written Authorization Requirements

Health and Safety Code Section 121015 permits (but does not require) a physician or surgeon who has an individual under his or her care to disclose that individual's confirmed positive HIV test result to the individual's spouse or any person reasonably believed to be the sexual or needle sharing partner of the individual, or to the local health officer. Such disclosure may be made only for the purpose of diagnosis, care, and treatment of the person notified or to interrupt the chain of HIV transmission. The disclosure must not include any identifying information about the HIV-positive individual.

Prior to disclosing an individual's test result, the physician or surgeon must discuss the results with the patient and offer appropriate emotional and psychological counseling, including information on the risks of transmitting HIV and methods of avoiding those risks. Further, the physician or surgeon must inform the patient of the intent to notify partners and must attempt to obtain the patient's voluntary consent for partner notification. Upon notifying a spouse or partner of an HIV-infected person, the physician or surgeon must refer the spouse or partner for appropriate care, counseling, and followup.

County health officers may notify a spouse or partner of an HIV-positive individual but cannot identify the infected individual or the physician making the report. As with physicians and surgeons, county health officers must refer the spouse or partner for appropriate care and followup. Upon completion of partner notification efforts, all records regarding the contacted person maintained by the county health officer, including but not limited to identifying information, must be expunged. The county health officer must keep confidential the identity and HIV status of the individual tested and the identity of the persons contacted.

ONE HUNDRED FIFTH CONGRESS

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U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

June 25, 1998

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

Congressman Coburn wrote to you on March 6, June 2, and June 16, 1998, concerning the compliance of States with respect to the notification requirements for spouses of HIV-infected individuals as provided by the Ryan White CARE Act Amendments of 1996. In his letters, Congressman Coburn expressed concern that States which have been certified to receive Ryan White CARE grants may not have enacted a spousal notification program in accordance with statutory requirements and Congressional intent. In each of his three letters, Congressman Coburn asked 1) if a State had not yet enacted a spousal notification program, how was that State certified to receive Ryan White CARE grants?, and 2) how do we know that other states which have been certified as complying were actually fulfilling this and other federal conditions necessary to be eligible for such grants? However, to date, no response has been received to *any* of Congressman Coburn's requests. Therefore, we are writing to you to follow-up on Congressman Coburn's previous letters and to request certain information and documents.

Specifically, Congressman Coburn's concerns stemmed from a January 25, 1998 article in the *New York Times* which stated that New York State's "existing policy prohibits caseworkers from notifying any sex partner, including spouses, without the voluntary consent of the HIV-positive person." Furthermore, the article stated that, "a Health Department spokesman, Fred Winters, said the spouse policy was 'under review.'" In addition, an article from the May 29, 1998 *New York Times* stated that "New Jersey's system of notifying partners is voluntary. Spouses or other partners of infected peoples are not notified without the consent of the infected person." Finally, Congressman Coburn recently came across a copy of "A Brief Guide to California's HIV/AIDS Laws 1997," which states that California law "permits (but does not require)" spousal notification.

We are very troubled by the Department's lack of attention and *any* reply to Congressman Coburn's requests, and are concerned that the Department believes that it is acceptable not to

respond to Congressional inquiries. As you will recall, we wrote to you on December 19, 1997 after the Department had failed to reply -- after eight months -- to another of Congressman Coburn's numerous requests. Furthermore, the Committee is becoming increasingly concerned that States are falling considerably short of complying with the Ryan White law, which states "the Secretary of Health and Human Services shall not make a grant under Part B of Title XXVI of the Public Health Service Act (42 U.S.C. 300ff-21 et seq.) to any State unless such State takes administrative or legislative action to require that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to the human immunodeficiency virus and should seek testing." We are very concerned that the approaches of the States mentioned above, and perhaps others, fail to meet the qualifications of a "good faith effort." Accordingly, pursuant to Rules X and XI of the U.S. House of Representatives, please provide the Committee the following information and documents by July 15, 1998:

1. Please explain why the Department has failed to respond *at all* to any of Congressman Coburn's requests.

2. Please provide all records related to the consideration, review and development of a response to Congressman Coburn's requests.

3. With respect to the concerns mentioned above related to New York's, New Jersey's, and California's programs, please explain how it is that these states, which apparently failed to enact a spousal notification program consistent with statutory requirements, were certified to receive Ryan White CARE grants?

4. Please provide the Department's justification for certification for each State and all documents related to the basis for such justification.

    a) Please explain in detail how certification was determined.

    b) Please provide a list of who made the certification determination for each State.

5. Please provide a complete list of the number of individuals that have been notified in each State.

    a) Please explain if there has been any follow-up to determine if States are actually conducting notification. If not, please explain why not?

6. Congressman Coburn also wrote to the Department on April 7, 1998, about his concern that States are receiving federal funding without following 42 U.S.C.300ff-47, which provides that no State will receive federal funding for HIV support services unless the State has implemented criminal laws sufficient to prosecute any HIV-infected individual who intentionally exposes another to HIV.

a) Please explain why the Department has failed to respond to this request.

b) Please provide all records related to the consideration, review and development of a response to this request.

c) Has this requirement been implemented? If not, please explain in detail why not?

d) With respect to compliance with 42 U.S.C. 300ff-47, please provide the following:

i) a copy of each State's completed certification form and "summary" provided to CDC and HRSA and the date it was originally submitted;

ii) whether each State's summary was determined to be in compliance with the statute as submitted and the date the Department made that determination; and

iii) if a State's proposal was found to be not in compliance as submitted, please explain in detail the deficiencies. If a State took subsequent steps to gain approval, please explain in detail the steps taken.

For purposes of responding to this request, the term "records," "relating," and "relate" should be interpreted in accordance with the Attachment to this letter.

If you have any questions, please contact Mr. Matthew Saylor, Committee counsel for oversight and investigations, at (202) 226-2424. We appreciate your cooperation in this matter.

Sincerely,

Tom Bliley
Chairman

Tom A. Coburn
Member of Congress

cc: The Honorable John D. Dingell, Ranking Member
The Honorable Joe Barton, Chairman
Subcommittee on Oversight and Investigations
The Honorable Ron Klink, Ranking Member
Subcommittee on Oversight and Investigations

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUL 9 1998

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515-3602

Dear Dr. Coburn:

Thank you for your letters regarding HIV program procedures in New York State, New Jersey, and California to address the spousal notification requirements of the Ryan White CARE Act Amendments of 1996. I apologize for the delay of this response.

The Centers for Disease Control and Prevention (CDC) requires documentation that every State health official has certified that a good faith effort will be made to comply with the provisions of P.L. 104-146, Section 8. A summary of these responses was previously provided to you on February 2, 1998. In addition, CDC's program announcement for HIV Prevention funding states that all HIV Prevention Cooperative Agreement recipients must comply with these requirements. New York, New Jersey, and California all certified to CDC that they were in compliance with the spousal notification provisions and provided appropriate documentation.

Regarding your inquiry about New York State, the January 25 *New York Times* article contains inaccurate information. In summary, the printed statement that a "policy exists that prohibits caseworkers from notifying any sex partner, including spouses, without voluntary consent of the HIV-positive person" is not accurate. New York State has strict regulations in place to protect the confidentiality of HIV-infected persons, but the law allows disclosure of HIV-related information to contacts even without consent. To clarify the procedures for the spousal notification program in New York, I am enclosing information provided by CDC.

Regarding your questions about New Jersey and California, both States have provided to CDC documentation of legislative or administrative procedures for notifying spouses of HIV-infected individuals, which is currently under review. CDC will forward to you directly under separate cover more detailed information.

CDC project officers routinely communicate with their assigned State, territorial, and large-city health departments on a variety of HIV prevention, education, and program issues, including partner notification issues. Through this ongoing communication, questions on this matter and related issues are addressed. As with other programs that require State certification, CDC relies on its State partners to ensure that materials submitted to CDC are accurate, absent information to the contrary, and remain in compliance with required guidelines.

When necessary, to determine if States are in compliance with Federal requirements as a condition of receiving Federal funds, CDC also utilizes several legislative tracking services ("Legislate" and "StateServ") that can monitor proposed State legislative developments, including pending changes or newly introduced bills. Use of several of these services is supported through cooperative agreements with the Association of State and Territorial Health Officials and the National Conference of State Legislatures. Furthermore, the Conference of State and Territorial Epidemiologists has also been consulted regarding the development and implementation of spousal notification policies and procedures.

I hope this information is helpful. We would be pleased to meet with you and your staff to further discuss this issue.

Sincerely,

Donna E. Shalala

Enclosure

INFORMATION CONCERNING NEW YORK STATE'S HIV PREVENTION AND SPOUSAL NOTIFICATION PROCEDURES

PREPARED BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Regarding the January 25, 1998, *New York Times* Article:

Mr. Fred Winters, who is quoted in the article as a Health Department spokesperson, is from the New York City Department of Health. However, he incorrectly represented policies relating to New York State partner and spousal notification procedures. Early in 1997, New York State certified its compliance with the requirements contained in Section 8 of Public Law (P.L.) 104-146. The New York City policy is consistent with the "good faith" effort requirements of the Ryan White CARE Act.

The printed statement that a "policy exists that prohibits caseworkers from notifying any sex partner, including spouses, without voluntary consent of the HIV-positive person" is not accurate. New York State has strict regulations in place to protect the confidentiality of HIV-infected persons, but the law allows disclosure of HIV-related information to contacts even without consent, as briefly described below.

Regarding New York State's Efforts to Ensure Spousal Notification:

The following are highlights of current New York State laws related to this issue and the good faith efforts that New York State is undertaking to comply with P.L. 104-146:

- Article 27F of the New York State Public Health Law states that during pretest counseling, a client must receive an explanation of the circumstances under which disclosure of HIV information may be authorized and permitted. This includes a physician's authority to notify partners under Section 2782.4 of Article 27F. This information is also included on the testing consent form. During post-test counseling provided to all clients receiving positive HIV test results, the law also requires that clients be told about the need to notify contacts.

- Under Article 27F, it further states that a physician may notify the partner of an HIV-infected individual without consent if the physician believes that disclosure is medically

appropriate; the partner/spouse is at significant risk of HIV infection; and it has been noted that the protected person will not inform the partner/spouse after being counseled to do so.

- This authority is extended to nurse practitioners and physician assistants as agents of physicians.

The following are program activities occurring in New York State to enhance the accessibility and ensure effectiveness of the partner/spousal notification program:

- New promotional materials have been developed, including brochures, posters, public service announcements, and information cards to improve the marketing of the assisted partner notification services (including spousal notification). This includes updated mailings to all physicians and programs that conduct HIV testing.

- All certified laboratories conducting HIV confirmatory testing include the following message on all HIV-positive laboratory reports:

  > Informing partners of HIV positive individuals of their exposure status is integral to HIV prevention efforts. New York State Public Health Law Article 27F authorizes providers to discuss and provide partner notification, including spousal notification. Local public health officials are available to assist with partner outreach programs. Call (518) 474-3598 for more information.

- In December 1997, the State Commissioner of Health sent a "Dear Colleague" letter to physicians, managed care organizations, contractors, and other regulated facilities providing HIV services in New York State regarding the importance of partner/spousal notification of HIV exposure, the relevant provision of Public Health law, Article 27F, the options for notifications, and the availability of educational materials and training programs addressing this topic.

- All New York State Department of Health AIDS Institute contractors providing HIV counseling and testing, primary care and case management receive a standard workplan that includes a partner/spousal notification goal with six objectives. The contractor is required, on an annual basis, to develop activities to address each objective for Partner/Spousal Notification Services.

New Jersey Department of Health and Senior Services
Spousal Notification Procedures
Response to CDC Inquiry

On January 13, 1997, the Division of AIDS Prevention and Control submitted an Assurance to the Centers for Disease Control and Prevention (CDC) asserting that the State of New Jersey is in compliance with Section 8 of Public Law 104-146 which states that recipients of Ryan White funding must make "administrative or legislative action to require that a good faith effort be made to notify a spouse of a known HIV infected patient that such spouse may have been exposed to the Human Immunodeficiency Virus and should seek testing".

CDC responded in a letter dated February 13, 1997 stating that they acknowledge "... receipt of the State's certification that the requirements for spousal notification of HIV exposure contained in Section 8 of Public Law 104-146 have been adequately addressed". This letter, signed by Mr. Gary West from CDC, certifies that New Jersey is in compliance with the requirements of the Ryan White CARE Act Amendments of 1996, which makes New Jersey eligible to receive assistance under Part B of Title XXVI of the Public Health Service Act (42 U.S.C. 300ff-21 et seq.)

The Assurance provided in the January 13th letter to CDC still accurately describes the activities carried out by the Division of AIDS Prevention and Control's (DOAPC) Notification Assistance Program (NAP). One modification to that Assurance concerns the proposed Assembly Bill 2448. This piece of proposed legislation was never enacted into law. While this law was not enacted, its provisions are already conducted by NAP. However, there are some additional activities carried out by the Division which further enhance DOAPC's provision of spousal notification activities.

For example, in a document entitled Identification and Management of Asymptomatic HIV-Infected Persons in New Jersey, health care providers are again reminded of the importance of notifying any and/or all contacts or partners of HIV infected patients. Health care workers are further informed to contact the Division's Notification Assistance Program to assist them with contact tracing and notification. This document was disseminated to all physicians and nurse practitioners licensed in the State of New Jersey.

Additionally, Division personnel conducted a thorough review of existing protocol and procedure manuals to assure that spousal notification continues to be a priority for all staff conducting NAP field investigations. This manual was updated and upgraded to further emphasize the criticality of this activity. Further, a full-time staff member has been designated to meet with field staff on a monthly basis to review all investigation reports to monitor this activity. This individual also

accompanies each field representative on a quarterly basis, again ensuring that this activity remains a critical component of the NAP investigations.

To further illustrate that spousal notification is a critical component of Division activities, the DOAPC's Epidemiological Service Unit's Security and Confidentiality Policy instructs staff to refer all physician inquiries regarding partner notification to NAP.

An additional notification activity implemented to help prevent perinatal HIV transmission is contained in N.J.A.C. 8:61-3.1. This regulation regarding HIV counseling and testing of pregnant women states, "... in the interest of protection of public health, the physician caring for the woman may make her test results known to the physician caring for her infant."

In summary, the Department believes that the activities delineated above and in the previous communications clearly demonstrate our continuing commitment and compliance with the above referenced requirement concerning spousal notification.

California Health and Safety Code
Section 121015

AIDS may be disclosed to any of the following persons without written authorization of the subject of the test:

(a) To the subject of the test or the subject's legal representative, conservator, or to any person authorized to consent to the test pursuant to subdivision (b) of Section 120990.

(b) To a test subject's provider of health care, as defined in subdivision (d) of Section 56.05 of the Civil Code, except that for purposes of this section, "provider of health care" does not include a health care service plan regulated pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2.

(c) To an agent or employee of the test subject's provider of health care who provides direct patient care and treatment.

(d) To a provider of health care who procures, processes, distributes, or uses a human body part donated pursuant to the Uniform Anatomical Gift Act (Chapter 3.5 (commencing with Section 7150) of Part 1 of Division 7).

121015. (a) Notwithstanding Section 120980 or any other provision of law, no physician and surgeon who has the results of a confirmed positive test to detect infection by the probable causative agent of acquired immune deficiency syndrome of a patient under his or her care shall be held criminally or civilly liable for disclosing to a person reasonably believed to be the spouse, or to a person reasonably believed to be a sexual partner or a person with whom the patient has shared the use of hypodermic needles, or to the county health officer, that the patient has tested positive on a test to detect infection by the probable causative agent of acquired immune deficiency syndrome, except that no physician and surgeon shall disclose any identifying information about the individual believed to be infected.

(b) No physician and surgeon shall disclose the information described in subdivision (a) unless he or she has first discussed the test results with the patient and has offered the patient appropriate educational and psychological counseling, that shall include information on the risks of transmitting the human immunodeficiency virus to other people and methods of avoiding those risks, and has attempted to obtain the patient's voluntary consent for notification of his or her contacts. The physician and surgeon shall notify the patient of his or her intent to notify the patient's contacts prior to any notification. When the information is disclosed to a person reasonably believed to be a spouse, or to a person reasonably believed to be a sexual partner, or a person with whom the patient has shared the use of hypodermic needles, the physician and surgeon shall refer that person for appropriate care, counseling, and followup. This section shall not apply to disclosures made other than for the purpose of diagnosis, care, and treatment of persons notified pursuant to this section, or for the purpose of interrupting the chain of transmission.

(c) This section is permissive on the part of the attending physician, and all requirements and other authorization for the disclosure of test results to detect infection by the probable causative agent of acquired immune deficiency syndrome are limited to the provisions contained in this chapter, Chapter 10 (commencing with Section 121075) and Sections 1603.1 and 1603.3. No physician has a duty to notify any person of the fact that a patient is reasonably believed to be infected by the probable causative agent of acquired immune deficiency syndrome.

(d) The county health officer may alert any persons reasonably believed to be a spouse, sexual partner, or partner of shared needles of an individual who has tested positive on a test to detect infection by the probable causative agent of acquired immune deficiency syndrome about their exposure, without disclosing any identifying information about the individual believed to be infected or the physician making the report, and shall refer any person to whom a disclosure is made pursuant to this subdivision for appropriate care and followup. Upon completion of the county health officer's efforts to contact any person pursuant to this subdivision, all records regarding that person maintained by the county health officer pursuant to this subdivision, including but not limited to any individual identifying information, shall be expunged by the county health officer.

(e) The county health officer shall keep confidential the identity and the seropositivity status of the individual tested and the identities of the persons contacted, as long as records of contacts are maintained.

(f) Except as provided in Section 1603.1 or 1603.3, no person shall be compelled in any state, county, city, or local civil, criminal, administrative, legislative, or other proceedings to identify or provide identifying characteristics that would identify any individual reported or person contacted pursuant to this section.

121020. (a) (1) When the subject of an HIV test is not competent to give consent for the test to be performed, written consent for the test may be obtained from the subject's parents, guardians, conservators, or other person lawfully authorized to make health care decisions for the subject. For purposes of this paragraph, a minor shall be deemed not competent to give consent if he or she is under 12 years of age.

(2) Notwithstanding paragraph (1), when the subject of the test is a minor adjudged to be a dependent child of the court pursuant to Section 360 of the Welfare and Institutions Code, written consent for the test to be performed may be obtained from the court pursuant to its authority under Section 362 or 369 of the Welfare and Institutions Code.

California DHS/OA
HIV Spousal/Partner Counseling and Referral Services Program

In FY 1997/98, the California Department of Health Services/Office of AIDS (DHS/OA) redirected $500,000 in general funds to develop a statewide HIV Partner Counseling and Referral Services (PCRS) program that will ensure that a good faith effort is made to notify, counsel and refer persons most at risk for contracting HIV, the sex and/or needle-sharing partners of confirmed HIV positive persons. The intended outcome of this new program is to offer HIV counseling to all HIV positive persons seeking medical services in California and to encourage these persons to voluntarily inform their partners of their exposure, either directly or through other public health interventions. Another outcome will be to offer sensitive and competent HIV counseling, education, antibody testing, and referrals to all HIV exposed partners.

In order to implement this program on a statewide level, the HIV Prevention Policy Section has collaborated with local HIV coordinators, local STD program coordinators, DHS Sexually Transmitted Disease Control Branch, DHS Local Assistance Branch, and CDC program directors and policy writers. The collaboration is developing PCRS guidelines and policies (last approved in 1988) which will be distributed to city, county, state and private providers to assure that all partner counseling and referral needs are met in an appropriate and expedient way.

The HIV Prevention Policy Section is contracting with the STD/HIV Prevention Training Center to offer training to HIV counseling and testing supervisors, HIV counseling staff, EIP counselors, and other program staff who will be directly involved in counseling HIV positive persons, eliciting exposed partner's names and other locating information, and conducting notification, counseling and referral services in the field. HIV surveillance staff who work directly with HIV positive persons and who may initiate a discussion of partners with these persons would also be appropriate for the HIV PCRS training.

During FY 1998/99, the DHS/OA will prepare to establish pilot projects in high incidence areas where local programs may need additional support in the development or expansion of existing services. Pilot projects will offer direct assistance to local health jurisdictions performed by Consulting Communicable Disease Representatives (CCDR). Their primary activities will be to respond to HIV PCRS requests by conducting interviews and field notification services, including counseling, testing and referrals. Additionally, CCDRs will develop or enhance local referral linkages between private and public health providers, provide expertise and input to the expansion of other DHS/OA HIV prevention projects (e.g., the HIV counselor training program, HIV prevention case management projects, and early intervention projects), and assist in the evaluation of local program operations. CCDRs will be stationed in their respective pilot jurisdictions and will also work in a regional capacity to respond to requests/needs throughout the state.

In time, it is anticipated that the guidelines will continue to be updated, counselor training will be expanded to include community based organizations and possibly private medical practitioners, and the pilot project will be enlarged to include additional counties.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUL 14 1998

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515-3602

Dear Dr. Coburn:

This is in further response to your letter to Health and Human Services Secretary Donna Shalala regarding HIV spousal notification procedures in New York State, New Jersey, and California as required by the Ryan White CARE Act Amendments of 1996. Secretary Shalala has asked the Centers for Disease Control and Prevention (CDC) to provide further follow-up information to you concerning New Jersey's and California's compliance with these requirements.

As mentioned in Secretary Shalala's July 9, 1998, (copy enclosed) letter to you, CDC requires documentation that every State health official has certified that a good-faith effort will be made to comply with the provisions of P.L. 104-146, Section 8. In addition, CDC's program announcement entitled "Human Immunodeficiency Virus (HIV) Prevention Projects" states that all recipients must comply with these requirements.

In 1997, the New Jersey Department of Health and Senior Services' Division of AIDS Prevention and Control certified that the State was in compliance with the Ryan White CARE Act Amendments related to spousal notification of HIV-infected persons and provided CDC with appropriate documentation of this certification. In follow-up to your recent letter that references an article in *The New York Times* stating that "New Jersey's system of notifying partners is voluntary...," we requested additional information from the New Jersey State health department. The enclosed information was provided, again stating their compliance with the requirements and describing procedures that the health department has taken to ensure that health care providers make a good-faith effort to notify spouses and other sex or needle-sharing partners of people who test positive for HIV infection.

The California Department of Health Services also certified and provided documentation in 1997 that the State was in compliance with the spousal notification requirements of the Ryan White CARE Act Amendments. Enclosed is a copy of California Health and Safety Code Section 121015, which was submitted in support of California's certification and describes the State law related to

the notification of spouses, sex, and needle-sharing partners of HIV-infected individuals. The intent of this section is to protect the confidentiality of HIV-infected people whose partners are to be notified and to hold physicians harmless in conducting partner notification. Both of these provisions clearly support spousal notification. Also enclosed is a document provided by the California Office on AIDS that describes their spousal/ partner counseling and referral services, which ensures that a good-faith effort is made to notify, counsel, and refer all persons at risk for contracting HIV.

I hope this responds to your concerns about these States' compliance with the spousal notification provisions. We look forward to further discussing this issue with you and your staff at the July 21 meeting.

Sincerely,

Stephen B. Thacker for

Claire V. Broome, M.D.
Acting Director

Enclosures

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

COMMITTEE ON COMMERCE
SUBCOMMITTEES:
OVERSIGHT AND INVESTIGATIONS
HEALTH AND ENVIRONMENT
ENERGY AND POWER

COMMITTEE ON SCIENCE
SUBCOMMITTEE:
ENERGY AND ENVIRONMENT

Congress of the United States
House of Representatives
Washington, DC 20515–3602

July 16, 1998

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Claire V. Broome, M.D.
Acting Director
Centers for Disease Control and Prevention
Atlanta, GA 30333

Dear Dr. Broome,

Thank you for your July 14th letter regarding HIV spousal notification procedures in the states of New York, New Jersey and California as required by the Ryan White CARE Act Amendments of 1996. I appreciate the information which you have provided and look forward to meeting with members of the CDC staff on July 21 to discuss this matter further.

In the June 25th letter that I sent with Congressman Tom Bliley to HHS Secretary Donna Shalala, we requested "a complete list of the number of individuals that have been notified in each State." I have not yet seen these number and would thus appreciate the following information for our upcoming meeting:

Since the enactment of the Ryan White CARE Act Amendments of 1996, in the states of New York, New Jersey and California, could you please provide the number of

(1) Individuals who have tested positive for HIV or diagnosed for AIDS;

(2) Individuals testing positive for HIV/AIDS who are— or were previously— married;

(3) Notifications that were made to current or former spouses of those testing positive for HIV/AIDS.

This data would be sufficient to answering my inquiries about these states' compliance with federal spousal notification requirements. I would assume that since these states have certified as complying, they would have this information readily available.

Thank you again for your assistance with this matter. If you have any questions, please feel free to contact me or Roland Foster of my staff at (202) 225-2701.

Sincerely yours,

Tom A. Coburn, MD
Member of Congress

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

SEP 17 1998

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515-3602

Dear Dr. Coburn:

This is in response to your letter requesting specific information about individuals in California, New Jersey, and New York who have tested positive for HIV infection, including those who are or were previously married, and notifications to their current or former spouses. We appreciated the opportunity for Dr. Helene Gayle and Mr. Gary West of the Centers for Disease Control and Prevention (CDC) to meet with you on this and other related issues on July 21. The following information is in further response to the specific questions raised in your letter.

(1) [Please provide the number of] individuals who have tested positive for HIV infection or been diagnosed with AIDS [in the States of New York, New Jersey, and California].

(Note: All 50 States, the District of Columbia, U.S. dependencies and possessions, and independent Nations in free association with the United States report AIDS cases to CDC.)

The following **AIDS cases** were diagnosed among adults and adolescents during the period of April 1, 1997, through March 31, 1998 (the most recent one-year period for which data are available) and reported to CDC. (These numbers may be lower than actual AIDS cases diagnosed because of reporting delays.)

	Males	Females	Total
New York	3,716	1,676	5,392
New Jersey	1,300	660	1,960
California	3,799	508	4,307

Through December 31, 1997, 27 States had laws or regulations requiring confidential reporting by name of all persons with confirmed HIV infection, in addition to reporting of persons with AIDS. Although New Jersey adopted HIV reporting in 1992, California and New York did not require HIV reporting in 1997 (New York has recently passed legislation adopting HIV reporting). As of June 1998, New Jersey had reported the

following **HIV cases** that were diagnosed between April 1, 1997, and March 31, 1998: 833 HIV cases among male adults and adolescents and 557 cases among female adults and adolescents for a total of 1,390 cases among adults and adolescents. As with AIDS case reporting, these numbers may be lower than actual cases diagnosed because of reporting delays.

(2) For these three States, [provide the number of] individuals testing positive for HIV/AIDS who are, or were previously, married.

Information on the marital status, either current or past, of persons reported with AIDS or HIV is not collected by these three States. However, CDC's Supplement to HIV/AIDS Surveillance (SHAS), a voluntary followup interview on reported cases of HIV or AIDS in parts of 12 States, does inquire about marital status; however, New York, New Jersey, and California are not among these participating States. During the period April 1, 1997, through March 31, 1998, SHAS interviews included 2,159 persons (1,582 males, 577 females). They reported themselves as:

Never Married	1,189	(55%)
Married	237	(11%)
Separated	194	(9%)
Divorced	302	(14%)
Widowed	86	(4%)
Common-law	43	(2%)
With Partner	108	(5%)

(3) For these three States, [provide the number of] notifications that were made to current or former spouses of those testing positive for HIV/AIDS.

Currently, State and local health departments do not have reporting systems in place that provide information on the number of spouses notified. Similarly, there is no national system for collecting comprehensive data on the number of spouses or other partners of HIV-infected individuals who are notified of their potential exposure to HIV. However, data from publicly funded counseling and testing sites from approximately 40 States indicate that more than 81,000 partners visited these publicly funded test sites in 1996 after they were notified, either by a partner or by a health care provider, of an HIV exposure. In addition, while complete 1997 data on partner and provider referrals are not available from all areas, partial year data indicate a significant increase in notifications over 1996. CDC is currently engaged in discussions with representatives of State and local

health departments to improve both the data collection and prevention services devoted to ensuring that spouses who may have been exposed to HIV are notified and offered appropriate services.

I hope this information is helpful.

Sincerely,

Claire V. Broome, M.D.
Acting Director

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

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Congress of the United States
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October 1, 1998

Inspector General June Gibbs Brown
Department of Health and Human Services
Office of the Inspector General
330 Independence Ave., S.W. Room 5250
Washington, DC 20201

Dear Ms. Brown,

I am writing to request your assistance in determining whether or not the Department of Health and Human Services is enforcing, and states are complying with, provisions of the Public Health Service Act.

As you may know, 42 U.S.C. Section 300ff-21 et seq. requires that states enact laws or regulations requiring that past and present spouses of individuals diagnosed with HIV infection be notified that they may have been exposed to the disease as a condition of receiving federal grants under Part B of the Ryan White CARE Act. It has come to my attention over the past year that some states which have been certified as complying with this federal law by HHS may be ignoring this requirement.

Beginning with correspondence sent on April 14, 1997, I have been pursuing HHS for information to determine if states are indeed in compliance. After a year and a half, I have received no conclusive evidence or data to prove HHS has effectively enforced this law. I would, therefore, request that the OIG conduct an investigation to determine if states are indeed conducting federal spousal notification as required under the Ryan White CARE Act Amendments of 1996 and to take the necessary actions against any state which has not.

I have included information which may be of assistance to your investigation.

I would request a response within one week of receipt of this letter.

If you have any questions, please feel free to contact me or Roland Foster of my staff at (202) 225-2701. Thank you for your attention to this matter.

Sincerely yours,

Tom A. Coburn, MD
Member of Congress

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAY 28 1999

The Honorable Thomas Coburn, M.D.
House of Representatives
Washington, DC 20515

Dear Dr. Coburn:

Enclosed is the completed draft report entitled, "The Ryan White CARE Act: Implementation of the Spousal Notification Requirement." We conducted this evaluation at your request.

As you are aware, Section 8 of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act calls for States to make a "good faith effort" to notify spouses of persons infected with the human immunodeficiency virus (HIV) of their possible exposure. There are no objective criteria to evaluate whether States' initiatives reflect "good faith" on their part. We therefore used States' plans as approved by the Centers for Disease Control and Prevention (CDC) as a starting point for reviewing State compliance with the good faith effort requirement.

First, we determined that all 50 States and the District of Columbia had in fact submitted plans to CDC and that CDC had approved them. Each of the plans reflected a combination of new and previously existing procedures to improve spousal notification.

We then looked at whether States have carried out the activities in their certified plans. We did this by reviewing the implementation actions in 11 State programs. We conducted on-site reviews in six States with large populations of persons infected with HIV; in five randomly selected States, we conducted telephone interviews with State partner notification staff. We collected documentation of State notification program structures and efforts in all States. In the six site visit States we also spoke with persons directly involved in partner elicitation and notification activities. By analyzing the documentation and other information collected in the interviews, we were able to determine that the 11 sample States have complied with their plans.

We did note, however, that there is little hard data to document the results of States' notification efforts. We are making several recommendations to CDC regarding ways in which notification procedures could be improved, particularly as they relate to private providers. Private providers are especially important to the notification process as they are the primary source of first contact with the medical system for persons with HIV.

Page 2 - The Honorable Thomas Coburn, M.D.

We have included charts at the back of the report which may assist in summarizing the information included in the report.

We are now in the process of soliciting comments on this draft report from the Health Resources and Services Administration and the Centers for Disease Control and Prevention. Once we receive and analyze their comments we will send you the final version. In the meantime, we want you to see our conclusions so far.

If we can be of further assistance, please feel free to contact me or have your staff contact Helen Albert, Director of External Affairs, at (202) 260-8610.

Sincerely,

June Gibbs Brown
Inspector General

Enclosure

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE RYAN WHITE CARE ACT

Implementation of the Spousal Notification Requirement

JUNE GIBBS BROWN
Inspector General

AUGUST 1999
OEI-05-98-00391

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Region V prepared this report under the direction of William Moran, Regional Inspector General and Natalie Coen, Deputy Regional Inspector General. Principal OEI staff included:

REGION	HEADQUARTERS
William Moran, *Regional Inspector General*	Elise Stein, *Program Specialist*
Nora Leibowitz, *Project Leader*	

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http://www.dhhs.gov/progorg/oei

EXECUTIVE SUMMARY

PURPOSE

To identify whether States are implementing their approved plans to ensure a good faith effort is made to notify spouses of persons infected with HIV of their possible exposure.

BACKGROUND

Section 8 of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act requires that any State receiving Ryan White Title II funding take administrative or legislative action to require a *good faith effort* be made to notify current and former spouses of known HIV-infected patients of possible exposure. A State that does not comply with this requirement will lose its Title II funding. Title II provides funds to States for health care and support services for those with HIV and AIDS. The total Title II appropriation for FY 1999 was over $709 million.

The requirement for States to make a "good faith effort" does not mandate that all spouses of HIV-positive individuals be notified, but does require States to establish procedures which facilitate faithful attempts to notify all impacted spouses.

States have administered HIV and STD partner notification programs which included spouses for many years. The activities to which States certified were both ongoing efforts and additions to their Partner Counseling and Referral Services programs that were designed to specifically address spousal notification requirements.

Each State provided the Centers for Disease Control and Prevention (CDC) with information on existing or planned legislative and/or administrative actions in order to comply with Section 8 requirements. The CDC approved the certifications of compliance submitted by all 50 States, the District of Columbia and U.S. territories. We reviewed all 51 State certifications in order to gain a firm understanding of the details of this program. However, for the purposes of this study, we assumed that CDC's approval of certifications indicates State activities constitute a good faith effort as required.

We focused on determining whether States were implementing the programs that CDC had certified. To accomplish this goal, we collected documentation and conducted site visits with State public health staff and HIV test site counselors in six States with high prevalence of HIV cases. Additionally, we interviewed and collected documentation from State public health staff in five randomly selected States.

This evaluation was conducted at the request of Congressman Thomas Coburn.

FINDINGS

The 11 Sampled States Have Taken Action on Their Approved Plans

All sampled States have followed up on certified activities, including revising counseling guidelines and contract language, updating training materials, retraining counselors and informing providers about changes due to Section 8 of the Ryan White CARE Act. Some States have initiated additional notification activities not contained in their original certifications.

States Are Responding to Common Barriers

Efforts to notify spouses and partners of persons with HIV are hampered by legislative and administrative barriers, by the structure of State and local governments and by physician, counselor and patient concerns. States have responded to barriers by offering freedom from liability for providers who notify, and by organizing elicitation and notification programs to fit into existing governmental and health care structures. Some States offer training for physicians and counselors, and make efforts to explain the process and benefits of notification to persons newly diagnosed with HIV.

Several States Are Undertaking Promising Notification Efforts

While all sampled States have done what they certified to, several States have taken actions which appear particularly useful or successful. Several States have made efforts regarding provider and counselor training, data utilization and notification that balance informing partners and maintaining confidentiality for index cases.

Data Collection Is Limited and Uneven

Five sampled States collect data on partner notification. However, none of the 11 sampled States collects data specifically on the number of spouses who have been notified of their HIV exposure risk. The six others currently do not collect notification data as part of their programmatic efforts. Three of these States are currently developing or piloting data systems. In at least one State which does not collect data at the statewide level, some counties collect local data on notification.

RECOMMENDATIONS

While States have taken action on their certifications, their efforts do not completely ensure that vulnerable people are always made aware of their possible exposure to HIV. Based on our findings, additional efforts need to be undertaken to ensure maximum notification while ensuring confidentiality and meeting patients' needs.

Continue to Facilitate Understanding of Notification Efforts Through Publicity, Education and Training

The CDC currently engages in public education efforts on a number of HIV-related issues. To increase knowledge for all parties, we recommend that CDC augment its current efforts by facilitating targeted education campaigns and provider trainings.

Establish and continue efforts to publicize notification goals, efforts and benefits. Publicizing information about notification and other Partner Counseling and Referral Services activities can increase awareness and broaden acceptance of the purpose and benefits of informing spouses and partners about their HIV risk. We recommend that CDC establish targeted public affairs efforts for providers, HIV advocacy groups and persons at high risk of contracting HIV. Spouse and partner notification should be addressed at senior levels in the department, and information about State efforts should be conveyed to interested parties in a manner that increases the issue's acceptability.

Facilitate local cooperation and collaboration. We recommend that CDC facilitate local level collaboration between State and local public health departments and private providers. Over 80 percent of HIV tests are conducted in the private sector. Training, technical assistance and other written and oral guidance can help public health departments and private providers understand the process of spouse and partner notification, their roles in the process and the benefits of partner notification.

Share Good Practices, Replicable Efforts

We recommend that CDC facilitate the sharing of information about successful State notification practices, including training, data collection and other efforts which enhance spouse and partner notification outcomes. The CDC should sponsor multi-State meetings on notification issues and efforts, and encourage the spread of promising practices.

Encourage the Establishment of Data Collection Systems

We recommend that CDC encourage the development and use of data collection systems to monitor State spouse and partner elicitation and notification efforts. Information collected provides a snapshot of efforts that are working and those that may need more attention. The agency should facilitate the development of pilot and full-scale data collection programs, identifying successful State data collection efforts and facilitating information sharing between States on notification data collection issues. Data on elicitation and notification can be aggregate information which does not require States to collect and store identifying information on partners or index cases. Due to the substantial costs involved in data collection, the above recommendation is contingent on the availability of funding.

AGENCY COMMENTS

We would like to thank the Centers for Disease Control and Prevention and the Health Resources and Services Administration for commenting on the draft of this report.

The Centers for Disease Control and Prevention suggested some additions and a change to the first recommendation. Based on their comments, some changes and clarifications were made to this report. In particular, at their suggestion we have attached their guidance to State public health officials regarding certification of compliance with the spousal notification requirement. These guidelines provide examples of principles and practices that constitute a "good faith effort" for certification. The full text of their comments is attached.

The Health Resources and Services Administration concurred with our recommendations and had no additional comments.

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INTRODUCTION

PURPOSE

To identify whether States are implementing their approved plans to ensure a good faith effort is made to notify spouses of persons infected with HIV of their possible exposure.

BACKGROUND

The Ryan White CARE Act

In response to the HIV epidemic and its impact on individuals, families, communities, cities and States, Congress passed the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act in 1990. Ryan White programs provide health care and support services to persons with HIV and AIDS who would otherwise not have access to care.

The Ryan White Act, which was re-authorized in 1996 through the year 2000, has four titles:

- Title I: HIV emergency relief grant program for cities
- Title II: HIV care grants to States
- Title III: Early intervention services
- Title IV: Pediatric care and reports and evaluations

Through its HIV/AIDS Bureau, the Health Resources and Services Administration (HRSA) administers the Ryan White program. The HIV/AIDS Bureau conducts programs to benefit low-income, uninsured and under-insured individuals and families affected by HIV/AIDS. Total appropriations for HRSA-funded CARE Act programs is $1.41 billion for fiscal year 1999.

Section 8 of the Ryan White CARE Act

Section 8 of the Ryan White reauthorization requires that any State receiving Ryan White Title II funding take administrative or legislative action to require a good faith effort be made to notify current and former spouses of known HIV-infected patients of possible exposure. A State that does not comply with Section 8 of the 1996 reauthorization of the Ryan White Act will lose its Title II funding. The requirement for States to make a "good faith effort" does not mandate that all spouses of HIV-positive individuals be notified, but does require States to establish procedures which facilitate faithful attempts to notify all impacted spouses.

While HRSA-administered Ryan White Title II funding is at risk for States which fail to comply with Section 8 of the Act, spousal notification falls under the purview of the Centers for Disease Control and Prevention (CDC). The CDC directly funds HIV/AIDS prevention activities through the agency's HIV Prevention Projects. These programs assist public health departments (1) to reduce or prevent the transmission of HIV by reducing or preventing behaviors or practices that place persons at risk for HIV infection; and (2) to reduce associated morbidity and mortality of HIV-infected persons by increasing access to early medical intervention. This funding is the primary source of HIV prevention funding for all State health departments and six city health departments.

Officials at HRSA have noted that States that fail to comply with Section 8 requirements will lose their Title II funding, despite the fact that CDC administers partner notification and other HIV prevention activities. Just as different Federal agencies administer Ryan White and HIV prevention programs, the agency administering Ryan White Title II funds at the State level is often different from the one conducting HIV and AIDS partner notification. Thus, the State agency responsible for funding health care and social services for persons with HIV may be forced to respond to a loss of funds without having any authority to fix the problem which caused the loss. A State that does not make a good faith effort to notify spouses and partners loses funds earmarked for HIV health and ancillary care services not money directed for prevention.

CDC Approval Process

In December 1996, CDC asked States and Territories to certify that they were taking legislative and/or administrative steps to ensure compliance with Section 8 of the Ryan White CARE Act (P.L. 104-146). The "CDC Guidance to State Public Health Officials Regarding Certifications of Compliance With Public Law 104-146" describing what constitutes a good faith effort accompanied the CDC request for State certification information. This document is included in Appendix B of this report. All States responded in January and February 1997. Each State provided CDC with information on existing or planned legislative and/or administrative actions. The CDC reviewed the documents and approved those found to be acceptable. The CDC worked with States whose certifications did not appear to meet compliance standards in order to develop compliance plans which would ensure a good faith effort. In letters sent on February 13, 1997, CDC acknowledged State certifications.

In our analysis of the steps States have taken to fulfill promises made in the certifications, we assumed that CDC's approval of certifications indicated State activities constituted a good faith effort as required.

All States: Certifications

The CDC has approved the certifications of compliance with P.L. 104-146 submitted by all 50 States, the District of Columbia, and U.S. Territories. The certifications indicated

what laws and policies each State currently had in place or intended to implement. Certifications cited existing State law, recently passed legislation and planned legislative changes as well as current policy, planned policy changes and current or planned attempts to publicize laws and policies.

Thirty State certifications made reference to current law or planned legislation which addressed spousal notification requirements. Forty-six States described policies and guidelines which were in place or which the State planned to implement. In addition, 20 States specifically described language regarding spousal notification which was already required for contracts and memoranda of understanding or which they intended to insert into such agreements.

Partner Notification in Context

States have administered Partner Counseling and Referral Services (PCRS) programs for many years. While these efforts include notification of spouses and other partners, they are not limited to such activities. The activities to which States certified were both ongoing efforts and additions to their PCRS programs which were designed to specifically address spousal notification requirements.[1]

In December 1998, CDC's National Center for HIV, STD and TB Prevention published a revised "HIV Partner Counseling and Referral Services" guidance document. The guidance provides information on availability of PCRS, advises programs developing a PCRS plan gives direction on locating and notifying partners, collecting and analyzing PCRS data and ensuring the quality of PCRS. While previous to this guidance States had their own guidelines and program rules for spouse and partner notification, many States run their programs and update their procedures using CDC's ongoing guidance.

Health departments and other organizations which provide PCRS to their clients offer services based on a number of core PCRS principles. As CDC indicates in their 1998 guidance document, PCRS must be voluntary, confidential and culturally sensitive. A PCRS program is one component of a comprehensive HIV prevention system, and is based on client-centered counseling which makes use of multiple support services and diverse referral options.

While this report focuses on two aspects of PCRS (elicitation of partner names and notification of those partners of their possible exposure to HIV), these elements are understood to be part of a comprehensive PCRS program. As CDC stresses in their guidance, counseling is the key to successful efforts to reduce HIV transmission and improve the health of currently infected persons.

[1] Also see Appendix B for examples of "good faith effort" principles and practices that CDC provided to State public health officials.

Eliciting names of spouses, sex partners and intravenous drug needle-sharing partners often takes place during post-test counseling, or at a session held shortly after diagnosis. Notification is generally, though not exclusively, carried out by State or local public health employees. It is always conducted in person and never involves identification of the index case to notified partners or other individuals. Elicitation may be performed by the same person who notifies spouses or partners, but this is not always the case.

Defining Index Cases and Partners

In the elicitation and notification process that is started when an individual tests positive for HIV, State public health staff often refer to the person tested as an "index case." This designation helps define the individual as someone who has tested positive for HIV and who is asked to name spouses and partners at the start of the notification process.

Many States' certifications do not specifically define partners, though many define "spouse" by referring to language used in Section 8 of the Ryan White CARE Act. States which do explicitly define partners in their certifications include spouses, non-spouse sex partners and individuals with whom persons share intravenous drugs and needles.

Notification of Spouses

None of the States in our sample or in the larger group of States and Territories which certified to the CDC runs a notification program which only notifies spouses about possible HIV exposure, but does not notify other sex or needle-sharing partners. Even States which made legislative and/or policy changes in order to comply with Section 8 of the Ryan White CARE Act already ran previously existing partner notification programs. To ensure compliance, States made changes to law and/or policy with regard to *spousal* notification specifically. Several States added language to their partner notification policies to specifically address Section 8 requirements.

This evaluation was conducted at the request of Congressman Thomas Coburn.

METHODOLOGY

We examined approved certifications from the 50 States and the District of Columbia. We reviewed the administrative and legislative actions each State had taken or planned to take to ensure compliance with Section 8 of the Ryan White CARE Act. We conducted on-site interviews with six higher prevalence HIV States (California, the District of Columbia, Florida, Illinois, New Jersey and New York). The site visits included discussions with State staff responsible for spouse and partner notification activities and with individuals directly involved in HIV counseling and testing at the local level. In addition, we conducted telephone interviews with State staff responsible for spouse and partner notification activities in five randomly selected States (Kansas, Missouri, North Carolina, Washington and West Virginia).

In each of the 11 States where we conducted on-site or telephone interviews, we discussed the State's current spouse and partner notification policies and laws. We also asked each State about the planned actions in their certifications to identify whether the State had taken action on these items. We collected documents regarding States' implementation of spousal notification programs.

We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

The 11 sampled States have taken action on their approved plans

All 11 States certified to planned activities

Each State certification describes existing and planned administrative policies.[2] Six of the 11 States cite laws that specifically refer to the notification of spouses of persons diagnosed with HIV. Certifications in six States outline where language regarding spousal notification was inserted into contracts and memoranda of understanding; seven States' certifications describe current or planned attempts to publicize notification rules and policies.

All sampled States have followed up on planned activities, including revising counseling and testing guidelines and contract language, updating training materials, retraining counselors and informing public and private providers about changes due to Section 8 of the Ryan White CARE Act.

Eliciting spouse and partner names from index cases

State or local health department employees are specifically employed to elicit names in seven sampled States. In these States, staff eliciting spouse and partner names may either be stationed at the counseling site or may contact the original patient using information provided by the physician or counselor. The latter is generally employed when a private provider has conducted an HIV test for a patient. Although elicitation is often performed by State or local public health staff in these seven States, it is the sole responsibility of the public health department in only one of them.

In four States, names are primarily elicited by physicians and HIV counselors at the time an individual's diagnosis is discussed. An HIV counselor may be employed by the State, local health department or a private agency.

[2]For further information on the activities States describe in their applications, see Table 1: "State Spousal Notification Efforts - Actions Described in Certifications" in Appendix C.

Notification duties and State partner notification staff

State or local health department staff have primary responsibility for notifying spouses and partners in all 11 sampled States. In over half the sampled States, physicians and HIV counseling staff may notify spouses and partners, although they do not usually have primary responsibility for this activity. In one State, the attending physician is responsible for ensuring that notification occurs, whether or not he performs this activity. In another State, providers are encouraged but not required to elicit names and notify spouses. This State's certification notes that State law frees them from liability whether they choose to notify or not.

The role of counseling in the elicitation and notification process

Respondents at the State and local level indicated that good counseling is the key to eliciting partner names and successfully educating partners about their risk and steps they can take whether or not they test positive for HIV. Counseling activities for both the HIV-positive individual and his or her partners are extremely important. Thorough counseling outlines the client's risk and facilitates the development of strategies to prevent further transmission of HIV. As CDC indicates, counseling takes substantial time, effort, training and resources. These investments are worthwhile, because clients who understands their risks and the possible danger they pose to others are more likely to fully participate in partner notification activities. State respondents indicated that counseling sites with more developed programs and better trained staff are more successful at eliciting partner names from their HIV-positive clients.

Spouses and notification without patient consent

Due to confidentiality laws, five States in our sample require patient consent for a provider to notify a spouse. In one State, a physician may personally notify a spouse only with patient consent, but can facilitate notification without consent. If a physician knows the identity of his HIV-positive patient's spouse, that physician is required to give the spouse's name to State staff responsible for notification. For non-spouse partners, patient cooperation with elicitation and notification is required.

While confidentiality laws restrict some State notification efforts, 8 of the 11 sampled States allow providers to notify spouses without the index case's permission if the provider knows the spouse's identity. Public health staff or the notifying physician are generally required to contact the index case and try to gain their consent before proceeding with notification.

Steps beyond certifications

In discussions with States about compliance with their spousal notification activities, respondents in four States described actions they have initiated since receiving approval of their certifications. One State is currently implementing a more formal notification process than the one for which it was certified. The old process relied on counselors and physicians to send spouse and partner names to the notification assistance staff, while the new process gives this staff more authority to initiate notification discussions with providers. The new process also puts more responsibility on counselors and physicians to elicit names or to initiate the elicitation/notification process through the State or local notification office.

One State, which already required providers to elicit names in post-test interviews, established an active surveillance program. Nurses hired by the State visit providers who have sent in names of new positives. They discuss spouse and partner name elicitation as well as appropriate patient care and available services with physicians. Providers document notification discussions in their case notes, and nurses encourage physicians to discuss notification with patients on an ongoing basis. The program is being expanded with nurses providing ongoing follow-up with physicians.

State public health staff in another State not only notify spouses and partners of potential exposure, but also offer to perform an HIV test for notified spouses and partners in their residence. This facilitates the elicitation of a second round of partners from an original index case. State notification staff have been very successful at eliciting names from the field cases they post-test counsel, increasing the number of potentially impacted individuals who can be notified.

Another State is currently piloting a counselor training program and data collection system. Using several of its larger counties as test sites, the State is training HIV counselors and local notification staff. This improves participants' ability to perform effective elicitation and notification as well as increasing their knowledge about HIV treatment and available services.

The State's AIDS office, in conjunction with the sexually transmitted disease control program's training center, provides the training to local public health departments. In addition to running a training program, the State helps localities to develop goals and objectives based on State expectations. After staff at publicly funded sites are trained, private providers and counselors may access the free training as well. Once providers, counselors and notification staff in the pilot counties have been trained, the program will be expanded to the rest of the State.

States are responding to common barriers[3]

Legislative and administrative issues

State laws limit who may be informed of an individual's HIV status and how such notification can occur. Several States have patient confidentiality laws which restrict the ability of providers or others with information about infected individuals to inform partners of potential exposure to HIV. Even when notification is not restricted for spouses, States require that confidentiality be upheld for the index client. Other States' administrative rules or policies disallow partner notification without patient consent.

Despite rules that limit notification without patient consent, the majority of sampled States do allow providers to notify known spouses of their potential HIV exposure. Eight States in our sample provide freedom from liability for providers who notify spouses of persons with HIV that they may have been exposed. The majority of these States allow notification of all partners; only two States grant freedom from liability for spousal notifications only. The rules surrounding such notifications vary among States, but providers are generally required to discuss notification with the patient and attempt to convince the individual to participate in the process before taking action to notify a spouse. Some States limit notification without patient consent to cases in which the provider knows the spouse's identity.

One way that States have tried to address the dual concerns of patient confidentiality and public health protection is to involve newly diagnosed individuals in the notification process. Some States that allow spousal notification without patient consent require counselors and providers to first try to gain patient consent before proceeding. If a tested individual still refuses to cooperate, providers in at least one State must inform the person that they will notify. The patient's wishes regarding whether the provider or State public health staff will conduct the notification must also be followed. In another State, patient consent is necessary for the physician to notify a spouse, but consent is not required for the physician to provide the spouse's name to the public health department.

Fitting notification into State structure

States' partner elicitation and notification programs are often shaped by States' HIV prevalence and the structure of their State and local governments. In one State with high HIV prevalence, HIV prevention staff decided that the most effective strategy was to place notification activities within the context of ongoing service provision. Rather than develop a parallel infrastructure, the State developed an elicitation and notification program structured around existing service providers and testing sites. State staff indicated that they wanted notification to fit into a larger system of care. They wanted

[3]Also see Table 2: "Barriers to Spousal Notification and State Solutions" in Appendix C.

people to see notification as a service rather than a burden. In addition, with such a large number of HIV-positive individuals, public health staff determined that the cost of a program not tied to existing structures would have been prohibitive.

Several sampled States have large areas with low HIV prevalence. Some of these States have decided that it is not economical for disease intervention staff to be stationed in every public testing site throughout the State. In two States, higher prevalence areas are staffed by State-funded staff, who are called in when needed to counsel individuals in other areas. Counselors at HIV test sites are also trained to elicit spouse and partner names. These counselors, as well as private physicians, are able to counsel individuals about the value of notifying partners.

In several States, the counties have a fair amount of autonomy regarding the administration of their health and social services. This county orientation can impede State attempts to use one program structure that runs identically in every locality. One State's notification program was developed as a framework within which each county can develop program details that fit the locality. To accommodate the county independence, the State allows each county to design its own notification program, but offers training to local HIV counselors and notification staff. Training includes information on what elicitation should entail as well as how to conduct notification and what notifiers should know about HIV treatment and available services.

Physicians and elicitation

While many people seek HIV testing from public health clinics, CDC estimates that over 80 percent of HIV tests are conducted in the private sector - by private providers using private laboratories. With a large percentage of HIV tests conducted by private providers such as physicians, barriers to physician participation in HIV spouse and partner notification can have a large impact on the success of a state notification program.

Physicians may fail to elicit partner names from their HIV-positive patients for several reasons. Physicians vary in their ability and motivation to ask patients about their partners; many private physicians do not have the time or inclination to elicit names. Many physicians test only a few patients a year and are not practiced in HIV counseling and name elicitation.

Respondents indicated that physicians may not see a role for themselves in HIV partner notification in part because they are used to the sexually transmitted disease (STD) notification model. Public health officers conducting STD elicitation and notification do not rely heavily on participation by private physicians. There is no established working relationship between the two groups, and physicians may not understand that their role is different with regard to HIV notification than it is with STDs.

Several States in our sample encourage physician participation by following up with providers who test individuals for HIV. Two States ask providers to return forms indicating their elicitation efforts. Another State employs nurses who conduct follow-up work with physicians reporting HIV cases.

Most States offer HIV counseling training to both private and public counseling and testing staff, and many make completion of a training program mandatory for anyone providing HIV counseling and testing. Although this may not ensure participation, it encourages it by increasing providers' notification-related knowledge and skill base.

Counselors and elicitation

Many HIV counselors are hesitant to push patients to engage in partner elicitation, as they do not want to alienate the patients. Many counselors are primarily concerned that an individual diagnosed with HIV seek needed services. They may not want to broach topics which may impact the patient's willingness to return for services. In addition, some providers may not entirely understand the partner notification process. They can not pass on correct information about confidentiality, voluntary notification and other issues if they are not clear about what is required or allowed in their State.

Many of our respondents at the State and local level indicated that the keys to successful partner elicitation are training and a "corporate culture" in which partner notification is valued. Counselors, physicians and those managing test facilities must recognize the importance of partner notification and understand the central role elicitation plays in that process. Public health staff in one State indicated that variance in testing sites' success at convincing individuals to supply partner names was based in part on the motivation provided by site managers. They suggested that while all counselors received the same State-sponsored trainings, some managers stressed elicitation more than others and created an organization-wide sense that elicitation is important and achievable.

Respondents from another State noted that counselors' skills, as well as their relationships with the communities they serve, are key to successful notification efforts. A skilled counselor who establishes a rapport with a client and clearly explains the benefits of notification can greatly improve the affected individual's willingness to reveal behaviors and names to an individual the client has just met.

Notifiers

All 11 States appear to do a good job with the actual notification of partners and spouses. Each State we interviewed has motivated, well trained notification staff. They have few problems locating and notifying the individuals on whom they receive information. Many States rely on HIV notification staff who have previously worked in sexually transmitted disease (STD) units. These individuals transfer their knowledge and many of their protocols from the STD field to HIV notification.

Patients

HIV spouse and partner notification can usually only proceed with the patient's consent and cooperation. Even an accommodating individual may not be able or willing to discuss partners when he is digesting the news of his HIV status. In addition, patients may lack information about partners from longer time periods. The tested individual may not have good information about an ex-spouse or partner he or she has not seen in years. Other patients may refuse to identify spouses due to domestic violence concerns.

A number of States have addressed patient cooperation issues by clearly identifying notification as a voluntary process. Several States make efforts to market spouse and partner notification as a service rather than an imposition. Most States require post-test counseling to include a discussion of the benefits of notification, a description of the process and an explanation of available services and participation options.

Several States are undertaking promising notification efforts

While all sampled States have taken action on the activities to which they certified, several States have taken actions which appear particularly useful or successful. In particular, several States have made efforts regarding provider and counselor training, data utilization and notification which balance informing partners and maintaining confidentiality for index cases.

Training

Respondents in several States indicated that training is a key to successful elicitation and notification efforts. While all State notification programs require their staff to be trained, some States take the additional step of requiring all HIV counselors involved in elicitation and notification to undergo State sponsored training in this area. One State which requires training for all HIV counselors indicates that this allows the State partner notification program to ensure that all counselors learn why notification is beneficial, how the process works and how to perform their part of the process.

Another State ensures participation by private providers through its program of active surveillance. Public health staff visit providers who report cases of HIV. They discuss notification and other HIV related issues. During these meetings providers are encouraged to participate in notification activities. Active surveillance visits can serve a dual purpose, training private providers to participate in spouse and partner notification and improving relationships between public health staff and private medical providers. Working together, the two parties can better understand the issues each one faces and help one another with the elicitation and notification process.

Utilizing data

Of the five States that currently collect information on partner notification activities, two States stand out in terms of the data they collect and the way they use it. These States collect a large amount of information about their notification efforts, including the number of index cases interviewed, the number of partners elicited and the results of partner notification efforts. This information is aggregate data intended to assess trends rather than track individual cases. The data helps partner notification staff monitor their success and determine areas in need of improvement.

These States take the additional step of monitoring the results of notification efforts in terms of whether notified partners agree to have an HIV test, whether partners have been tested in the past and the results of previous and new tests. The data collected is aggregated to help State notification programs assess whether a broad approach to partner notification is effective in identifying new cases of HIV. A high percentage of notified partners identified as "never previously tested" or "previous negative test, new positive test" would suggest that notification efforts are successfully locating previously unidentified cases of HIV. If many notified partners test negative for HIV, this could suggest that the public health department may want to further target its HIV identification efforts.

One of the two States that collects a lot of notification data also gathers information on the success of elicitation efforts. Elicitation is primarily performed by counselors at HIV testing sites, and some sites receive State grants for their testing efforts. The State monitors the success of counselors at each site in eliciting partner names from persons newly diagnosed with HIV. Each site that receives State funding is required to maintain a 1.0 partner index, meaning that on average, each site must elicit at least one partner name from each interviewed patient. Collecting this information allows the State partner notification program to assess which sites are successful at partner elicitation. The State program can help less successful sites perform better by offering or mandating retraining sessions for counselors and suggesting that lagging sites emulate practices utilized by the more successful sites.

Balancing public health and confidentiality concerns

While some States use their HIV name reporting system to initiate spouse and partner notification efforts, partner notification can be conducted without linking it to a State surveillance program. In one sampled State, the public health department conducts a strong HIV spouse and partner notification program not connected to surveillance efforts. This State appears to have success notifying spouses and partners of their possible exposure to HIV by developed a program that balances the public health need to notify partners of possible exposure and the concern that confidentiality is assured for index cases. Although the State employs name reporting of HIV, the partner notification program is administered separately from the name reporting program. The separation allows notification staff to assure index clients that any information they provide about partners can not be linked back to them. Partner names and locating information are separated from patient information by testing site staff and given to the State health department staff responsible for notification. The notification field staff never learn the names of the individuals who provided the partner names, so they are not able to pass those names along even if they wanted to.

Data collection is limited and uneven

Although public health notification staff have a sense of their success at elicitation and notification, States often do not collect data in this area. None of the sampled States collects information on whether elicited partners are spouses or ex-spouses of index patients. Demographic information linking contacts to the index cases who name them is not collected in many States. One reason data on a partner's relationship to an index case is not collected is that this information could jeopardize confidentiality for the index case.

One sampled State collects information on how many notified individuals are currently married, but their confidential notification system does not allow them to link partners and index cases. Partner information is collected at the HIV test site and transferred to the partner notification field staff without any information about the index case. If an individual is recorded as the spouse of the index case who named him, the index case's identity can be readily discerned.

Five of the 11 sampled States collect data on partner notification.[4] Although each State collects somewhat different information, most of these States monitor the number of referred cases which result in a notification discussion, the number which result in spouse/partner elicitation, total contacts elicited and average contact index. Two States also collect information on the disposition of the notified case, including whether the

[4]For information on what types of data States collect, see Table 3: "Data Collection in the 11 Sampled States" in Appendix C.

partner or spouse had been previously tested and whether notification led them to get tested. The six other States in our sample currently do not collect data on spouse and partner notification as part of their programmatic efforts. Three of these six States are currently developing or piloting data systems. In at least one of the States which does not currently collect data at the statewide level, some counties do collect local information on notification activities.

RECOMMENDATIONS

States have been conducting spouse and partner HIV notification as part of PCRS and other counseling programs for many years; some programs were established in the mid 1980s. The planned and ongoing efforts States described in their 1997 certifications to CDC stemmed from States' larger public health mission to protect both HIV-infected persons and their partners. The certified activities were actions the States planned on implementing, and we found that the States in our sample have taken action on their certified activities.

This does not mean that spousal and partner notification has achieved its goal of ensuring that vulnerable people are always made aware of their possible exposure to HIV. Based on our findings, additional efforts need to be undertaken to ensure maximum notification while ensuring confidentiality.

As States have primary responsibility for public health issues and private physicians have primary responsibility for testing and initiating the notification process, we make the following recommendations to CDC:

Continue to facilitate understanding of notification efforts through publicity, education and training

The goals of partner notification are prevention of HIV transmission and improvement of HIV-infected persons' access to care. For partner notification to work, it requires participation by all parties - counselors, physicians, patients. This is most likely to occur when participants are educated about the process and benefits of partner notification. The benefits for providers, counselors, HIV-positive individuals and their partners should be stressed.

The CDC currently engages in public education efforts on a number of HIV-related issues. To increase knowledge on all sides, we recommend that CDC augment its current efforts by facilitating targeted education campaigns and provider training opportunities.

Establish and continue efforts to publicize notification goals, efforts and benefits

Misconceptions about spouse and partner notification are often due to lack of information. Providing information on notification and other elements of PCRS can increase awareness about the intent and benefits of informing spouses and partners about their HIV risk. Increased knowledge is key to clearing up the misconceptions, fears and mistrust that hamper participation by providers and patients.

Information about notification efforts and processes should be tailored to specific audiences. Specifically, physicians and other providers should be educated about their role in eliciting partner names and notifying affected persons. Providers need information about what spouse and partner notification entails, how it occurs in the provider's State, what its benefits are and the ways in which providers can participate.

Educational efforts should also be aimed at organizations which represent and advocate for persons affected by HIV and AIDS. As these organizations communicate with the HIV/AIDS community and with subgroups within the larger affected population, increasing knowledge at the organizational level can improve individuals' understanding of notification efforts and willingness to participate in the process.

For information on spouse and partner notification to be heard and accepted by the population at large, it must come from individuals who command respect by a given population. The message's acceptance will hinge on the speaker's legitimacy with the listeners. In addition, efforts to publicize this information must be targeted, the message clear. A message that is simple, easy to comprehend and explained by a trusted speaker has the best chance of convincing individuals to participate in spouse and partner notification for HIV.

In order to publicize the process and benefits of spouse and partner notification, we recommend that CDC establish targeted public affairs efforts. Spouse and partner notification should be addressed at senior levels in the department, and information about State efforts should be conveyed to interested and affected parties in a manner that increases the issue's acceptability. Programs should complement CDC and other efforts currently underway.

The CDC currently funds State efforts to increase individuals' knowledge of their HIV status. Much of the funds go to health departments to support the development of new and innovative early identification strategies to reach high risk populations and create linkages with care. Special emphasis is placed on projects that target minority populations, including women and adolescents. Funded activities may include coalition building, product development, outreach activities, and evaluation of effective interventions.

The funds are also used to promote risk reduction interventions to help those uninfected to stay that way, and to encourage those infected to practice safe behaviors to prevent the spread to others. The Secretary's Emergency Fund for HIV/AIDS funds such projects.

Facilitate local cooperation and collaboration

Respondents at the national, State and local levels indicated that cooperation between State health departments, private groups and individuals is necessary for a successful notification program. Cooperative efforts require good working relationships.

Unfortunately, several respondents indicated that private and public health professionals in many States do not have strong relationships. Efforts to strengthen these relationships and improve knowledge can greatly improve outcomes for elicitation and notification efforts.

We recommend that CDC facilitate local level collaboration between State and local public health and private providers through State medical societies, nurse practitioner groups and other provider groups. The CDC can encourage State and local public health agencies to facilitate this process by continuing to offer guidance and training to public health departments. Private providers should be encouraged to participate in trainings and other information sharing efforts. This is especially important as at least 80 percent of HIV tests are conducted in the private sector, yet these providers are often not linked to the State or local notification systems. Trainings, technical assistance and other written and oral guidance can help public health departments and private providers understand the process of spouse and partner notification, their roles in the process and the benefits of spouse and partner notification. Such efforts can also encourage public health and private providers to work together to improve their relationships in ways which smooth the process of notification.

Share good practices, replicable efforts

While each State has unique issues which stem from governmental structure, program needs, affected population and State laws, some public health practices can be successfully utilized in multiple locales with only small variations. We recommend that CDC facilitate the sharing of information about successful State notification practices, including training, data collection and other efforts which enhance spouse and partner notification outcomes. The CDC should sponsor multi-State meetings on notification issues and efforts, and encourage the spread of promising practices. As this is an area in which CDC has experience, current conferences and meetings can be utilized for information sharing purposes.

Encourage the establishment of data collection systems

Data can be a useful part of a State's spouse and partner notification program. Information collected on elicitation and notification efforts provide a snapshot of what efforts are working and which areas may need more attention. Data can encourage HIV counselors, private providers and public health staff who are successful at eliciting and notifying spouses and partners. It can also be used to provide benchmarks against which struggling providers and programs can measure themselves.

There may be reasons why a successful notification program may elicit and notify few partners. Some newly identified HIV cases may elicit few contacts because the individual may have had a limited number of partners. Similarly, notification efforts are affected by the quality of elicited information, which is impacted by the time period between an individual's last contact with a partner and the date they are asked for information. Memory is fallible, and people move, change names and die.

The fallibility of data aside, data collection can help recognize successful efforts, encourage providers, counselors and others involved with notification, and help identify areas for improvement in elicitation and notification.

We recommend that CDC encourage the development and use of data collection systems for spouse and partner elicitation and notification. The agency should facilitate the development of pilot and full-scale data collection programs by informing States of key data elements and collection procedures, by identifying successful State data collection efforts and by facilitating information sharing between States on notification data collection issues.

Although some States do conduct their notification programs in conjunction with their HIV surveillance efforts, data collection does not require the collection and storage of partner names or identifying information. Most States which collect elicitation and notification data aggregate their information in order to get a sense of trends and successes. Analysis of this data does not call for personal information on index cases or partners, as indicated by the work of one State which completely separates its HIV surveillance data from its elicitation and notification information.

Comments on implementation costs

The OIG recognizes that our recommendations have costs to States and the Federal government. The publicity and trainings we recommend require State and local partner notification staff to be hired and trained and private providers to be trained and included in public program efforts. Successful public awareness programs will increase costs associated both with locating, counseling and interviewing HIV-infected persons and their

partners and with program administration. Successful campaigns will encourage more providers to refer patients to participate in partner notification efforts. Additionally, instituting data collection programs could significantly increase costs to local, State and Federal governments.

We are uncertain of the cost of fully implementing the recommendations we have made. Few cost estimates exist on partner notification. In 1997, CDC estimated that fully implementing partner notification services using existing notification guidelines would require an additional national outlay of at least $20-30 million. This amount does not include the cost of establishing State data collection systems or conducting targeted public awareness campaigns. Additionally, CDC notes that resources to perform a comprehensive PCRS program are inadequate to meet current needs. The CDC estimates that the cost of implementing OIG's above recommendations would require an outlay which is two to three times current resources.

The OIG recognizes the substantial costs involved in the development and use of data collection systems and the implementation of public awareness campaigns. Our recommendations are contingent on the availability of funding for such efforts.

AGENCY COMMENTS

We would like to thank the Centers for Disease Control and Prevention and the Health Resources and Services Administration for commenting on the draft of this report.

The Centers for Disease Control and Prevention suggested some additions and a change to the first recommendation. Based on their comments, some changes and clarifications were made to this report. In particular, at their suggestion we have attached their guidance to State public health officials regarding certification of compliance with the spousal notification requirement. These guidelines provide examples of principles and practices that constitute a "good faith effort" for certification. The full text of their comments is attached.

The Health Resources and Services Administration concurred with our recommendations and had no additional comments.

APPENDIX A

Centers for Disease Control and Prevention Comments on the Draft Report

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date JUL 2 6 1999

From Acting Director, Office of Program Support

Subject CDC Comments on the Office of Evaluation and Inspection, Draft Report, "The Ryan White CARE Act: Implementation of the Spousal Notification Requirement" (OEI-05-98-00391)

To June Gibbs Brown
Inspector General

Thank you for the opportunity to review the draft report. In general, the report accurately describes the steps taken by CDC to certify states' implementation of spousal notification procedures required by the Ryan White CARE Reauthorization Act of 1996. It shows that CDC followed the law and used reasonable procedures. It also frames the statute's spousal notification requirements in the larger context of states' ongoing partner notification efforts. Below for your consideration are additional comments on the report.

1. CDC Approval Process: The draft report makes reference to the guidance document that CDC sent the states prior to the certification process, but does not provide the text of CDC's statement of minimal public health principles and practices that constitute a "good faith" spousal notification effort. There has been much confusion and some misunderstanding on the good faith concept, but this CDC statement has held up well and remains a key concept in the process. A copy of these principles should, at the minimum, be attached or appended to the final report. The OIG has previously been provided with a copy of these principles.

2. The words, *elicitation* and *notification,* used in describing what was called partner notification are too limited. Although they are important component of the service, now more properly referred to as Partner Counseling and Referral Services (PCRS), the concept that workers merely elicit names and then perform notification services is short sighted. The counseling activities are extremely important to a complete understanding of the client's risk and to develop a client-centered strategy to prevent further transmission of HIV. Counseling has to come first and takes time, effort, training and resources. Counseling is of immeasurable value in understanding how the infection was acquired, identifying others who might be at risk, and imparting information for understanding and minimizing risky behaviors. A client who understands his/her risks, and the potential dangers they pose to others, is much more likely to participate fully in referring others for counseling and testing. Likewise, the section of the report that describes notification efforts fails to address the related prevention outcomes. In cases where the partner has not become infected, such notification often has a beneficial prevention effect that reduces future risk practices and involves the couple in informational counseling and education.

APPENDIX A

Centers for Disease Control and Prevention Comments on the Draft Report

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3. Comments on Implementation Costs: The draft report does not adequately address the cost of a comprehensive PCRS program, and does not seriously mention cost until page 22. The additional costs noted there, however, are two or three times the amount current resources. Resources to perform PCRS are inadequate to meet current needs; increasing notification, examination and counseling standards for partners will require larger expenditures to improve the quantity and quality of those services.

4. RECOMMENDATIONS: The suggestion to stage a public information campaign needs refining. While CDC wants to increase the number of persons who know their HIV serostatus, programs publicizing PCRS for the general public run the real risk of crowding counseling and testing sites with legions of the "worried well." This clogs the system for persons who are truly at high risk, consumes precious resources, and results in a degradation of the entire scope of PCRS services. Information on counseling and partner notification services should be targeted to segments of the population who are much more likely to encounter these programs. In general, the most cost-effective opportunity to expound the value of these services occurs when a partner is being notified of his/her exposure, or when a positive client is offered PCRS during his/her counseling service. A friendly, well-trained health worker can tailor the message to fit the location, urgency and circumstances of clients and/or their partners.

Please contact Carolyn Russell, Director, Management Analysis and Services Office, (404) 639-0440, if you should have any questions regarding these comments.

James D. Seligman

APPENDIX B

CDC Guidance to State Public Health Officials Regarding Certifications of Compliance with Public Law 104-146

Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA)

Examples of Principles and Practices Regarding HIV Spousal Notification that Constitute a Good Faith Effort

SUMMARY: On May 20, 1996, the Ryan White CARE Reauthorization Act was signed into law (P.L. 104-146). Section 8(a) requires that States take "administrative or legislative action to require that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to the human immunodeficiency virus and should seek testing." Under this section, States that fail to take administrative or legislative action will be ineligible to receive grant funds under Part B of the Ryan White CARE Act administered by HRSA.

Currently, CDC requires all health department recipients of HIV prevention funding to "establish standards and implement procedures for partner notification consistent with State/local needs, priorities, and resource availability."

States must certify to CDC that they have taken the administrative or legislative actions necessary to require a good faith effort to ensure that spouses of known HIV-infected individuals are notified of their possible exposure to HIV and referred for testing.

All identifying information regarding HIV-infected patients and spouses must be kept confidential. No personally identifying information shall be disclosed unless required by State law or political subdivision, or unless the individual provides written, voluntary informed consent. Anonymous HIV testing does not preclude effective partner or spousal notification. Unless prohibited by State law or regulation, reasonable opportunities to receive HIV-antibody counseling and testing services anonymously should continue to be offered. Anonymous testing services may encourage some persons at risk of HIV, who might otherwise be reluctant to be tested, to seek testing.

The following are examples of public health principles and practices that constitute a "good faith" spousal notification effort by States. States should review these examples, but are not limited to them in considering which policies, systems, or actions will be appropriate for their jurisdictions.

APPENDIX C

Spouse and Partner Notification Activities: State Level Data

1. Individuals reported to the State on or after April 1, 1997, as diagnosed with AIDS (or HIV infection in States requiring HIV-infection reporting by law or regulation), if not already determined by the reporting health care provider, each such individual shall be a) asked if they have, or have had, a spouse (defined by this law as "any individual who is the marriage partner of an HIV-infected patient, or who has been the marriage partner of that patient at any time within the 10-year period prior to diagnosis of HIV infection"), and b) informed that he or she should notify their spouse, or former spouse(s), of the potential exposure to HIV.

2. Reasonable efforts must be made to determine if each HIV-infected individual intends to notify his or her spouse of their possible exposure to HIV or agrees to have a qualified health care provider notify them. In situations where the HIV-infected individual reports that he or she intends to notify the spouse, culturally competent counseling and educational services on the following issues should be available--how to make the notification, how to preserve confidentiality of both the individual and the spouse, how HIV infection and transmission can be prevented, and how the spouse can access testing, other prevention services, and treatment. If the HIV-infected individual is unable or unwilling to notify his or her spouse, culturally competent services should be available from the provider or the health department to do so. Unless covered by existing law, policy, or regulation, States should develop policies that address situations involving HIV-infected individuals who do not plan to notify their spouses and who refuse health department assistance. In developing these laws, policies, or regulations, States should consider guidance contained in *Guide to Public Health Practice: HIV Partner Notification Strategies* (Association of State and Territorial Health Officials, et. al., 1988). Notification is not necessary in situations where, in the judgement of public health officials, there has been no sexual exposure of a spouse to a known HIV-infected individual during the relevant time frame.

3. Reasonable procedures to ensure that notified spouses receive referrals for HIV testing, other prevention services, and treatment should be implemented.

4. Health departments that document spousal notification policies and practices of public and private health care providers reporting AIDS and HIV that meet State requirements or establish agreements with them for this purpose need not directly contact every HIV-infected individual reported by such providers for purposes of spousal notification.

Table 1: State Spousal Notification Efforts - Actions Described in Certifications 32

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APPENDIX C

Spouse and Partner Notification Activities: State Level Data

Table 1: State Spousal Notification Efforts - Actions Described in Certifications[5]

Action Description	Action Type	State/States
ALLOW NOTIFICATION This includes: freedom from liability for notification and active responsibility to make a good faith effort to notify or facilitate notification.	Legislative	AL AZ CT DE GA HI ID IL IN IA KS KY LA ME MD MI MS MO NH NY OH RI SC TN UT VA WI WY
	Administrative	AL AK AZ AR CA CO DE DC FL IN MA MN MT NE NV NH NJ NM NY NC ND OK OR PA SD TX VT WA WV
REQUIRE OR OFFER COUNSELING ON NOTIFICATION Most, if not all, States appear to do this to some degree, but not all States codify this in law. Other States have policies regarding notification counseling, but not all have noted these policies in their certifications.	Legislative	AL FL MD MS NY VA
	Administrative	AL AK AR CO CT DE DC GA HI IL IN IA KS MA MI MN MO MT NV NH NJ NM OH OK OR SD TN TX UT VT WA WV WI
OUTLINE PROVIDER AND PUBLIC HEALTH STAFF PARTICIPATION Some States put an affirmative duty on the public health department, private physicians or the person performing post-test counseling to carry out notification.	Legislative	AL AK CT ID MD MI MS NV NH NC SC WY
	Administrative	AZ CO DE DC FL HI IN IA KS KY LA ME MA MN MT NV NH NJ NM NC ND OH OK SD TX UT VT VA WY WI

[5]This table is based on information provided to the CDC by States. Some State certifications contained attachments which were not available to OIG during our analysis. Any information contained in such an attachment may be missing from the information provided in this table.

APPENDIX C

Spouse and Partner Notification Activities: State Level Data

Table 1: State Spousal Notification Efforts - Actions Described in Certifications, continued

Action Description	Action Type	State/States
REPORT HIV CASES FOR PUBLIC HEALTH PARTNER NOTIFICATION FOLLOW UP	Legislative	AK MS MO NY[6]
	Administrative	CO[7] CT IA MN NH OK SC SD WV[8] WI
REQUIRE VERIFICATION OF A NOTIFICATION PERFORMED BY AN INDEX CASE	Legislative	OK
	Administrative	AL CO MN TN WV WI
ENSURE CONFIDENTIALITY	Legislative	CA CT NY VA
	Administrative	CO DE DC ID LA MA MT NJ NM NC OH OK SD TN TX WY
UTILIZE CDC GUIDELINES, FORMS	Administrative	AL AK AR ID NH
REVISE NOTIFICATION LAWS, POLICIES, GUIDELINES TO ADDRESS SPOUSAL REQUIREMENTS	Legislative	MD
	Administrative	AK AZ CA[9] CO DE FL IA KS KY NE LA MA MI MO MT NV NH NM NY ND OR PA RI SC TX UT WA WV WI WY

[6]This is part of the new law under implementation in New York.

[7]Verification is performed if the HIV-positive individual agrees to participate in notification and wants to notify their spouse/partner on their own.

[8]Follow-up occurs for persons tested in the private sector. Persons tested in the public sector automatically receive notification counseling.

[9]The State encourages local programs to change the language in their guidelines, policies, etc. to address spousal notification issues.

APPENDIX C

Spouse and Partner Notification Activities: State Level Data

Table 1: State Spousal Notification Efforts - Actions Described in Certifications, continued

Action Description	Action Type	State/States
DISCUSS SPOUSES AND PARTNERS These State certifications specifically indicate that HIV counseling includes discussion of both individuals' partners and spouses and notification issues generally.[10]	Administrative	AL AK AR CO CT DE DC FL HI IL IN IA KS KY LA ME MA MI MN MS MO MT NE NV NH NJ NM ND OH OK OR SD TN TX VA WA WV WI
AMEND CONTRACTS AND MEMORANDAS OF UNDERSTANDING (MOUS)	Administrative	AL AK AZ CA CO CT DC FL HI ID IL IN KS LA MA MO MT NE NV NH NM ND OH OR PA TX UT WV WI
PUBLICIZE RULES, LAWS, POLICIES	Administrative	AL AK AZ AR CA CO CT DE DC FL HI IL IN KS KY LA ME MD MI MN MS MT NE NV NH NM NY ND OH OR PA TX UT WV WI
REVISE TRAINING AND TRAINING MATERIALS	Administrative	AK AZ CA IN KY MA NV NM NY RI TX WA

[10] Although State programs generally require or encourage this in their counseling guidelines, not all States mentioned it in their certifications.

APPENDIX C

Spouse and Partner Notification Activities: State Level Data

Table 2: Barriers to Spousal Notification and State Solutions

Issue	Description	State Solutions
Legislative and Administrative Barriers	State laws (including patient confidentiality laws) limit who may be informed of a person's HIV status and how such notification can occur. Most States require that the identity of the index case not be revealed through HIV notification. Some States' administrative rules or policies disallow partner notification without patient consent.	Address both patient confidentiality concerns and public health protection by involving newly diagnosed individuals in the notification process. Require counselors and providers to first try to gain patient consent before proceeding with notification without patient consent. If a tested individual refuses to cooperate, the provider must inform the person that they will notify. The patient's wishes regarding whether the provider or State public health staff will conduct the notification must also be followed.
Fitting Notification into State Structure	States' partner elicitation and notification programs are often shaped by States' HIV prevalence and the structure of their State and local governments. Designing a program without taking local issues, strengths and weaknesses into account will hinder program success.	States with high HIV prevalence: Structure the notification program around existing service providers and testing sites. With many HIV-positive individuals, the cost of a program not tied to existing structures may otherwise be prohibitive. States with low HIV prevalence: Augment efforts by State-funded staff with private HIV test site counselors trained to elicit names. County autonomy: Develop a framework notification program within which each county can develop program details to fit the locality. Each county designs its notification program; the State can offer training to local HIV counselors and notification staff.

APPENDIX C

Spouse and Partner Notification Activities: State Level Data

Table 2: Barriers to Spousal Notification and State Solutions, continued

Issue	Description	State Solutions
Physicians and Elicitation	The Hippocratic oath orders physicians to "tell no secret" obtained through the therapeutic relationship. Physicians vary in their ability and motivation to ask patients about their partners; many private physicians do not have the time or inclination to elicit names. Many physicians test only a few patients a year and are not practiced in HIV counseling and name elicitation.	Encourage physician participation by following up with providers who test individuals for HIV. Ask providers to return forms indicating their elicitation efforts. State-hired nurses who conduct follow-up work with physicians reporting HIV cases. Offer HIV counseling training to private and public counseling and testing staff. Make completion of a training program mandatory for anyone providing HIV counseling and testing. Encourage participation in the notification process by increasing providers' notification-related knowledge and skill base.
Counselors and Elicitation	Many HIV counselors are hesitant to push patients to elicit partners, as they do not want to alienate the patient. Many counselors do not want to broach topics which may impact the patient's willingness to return for services. Some providers may not entirely understand the partner notification process.	Stress counselor training and a "corporate culture" in which partner notification is understood and valued. Counselors, physicians and those managing test facilities must recognize the importance of partner notification and understand the central role elicitation plays in that process. Counselors' skills and the relationships they establish with the community are key to successful notification efforts. A skilled counselor establishes a rapport with a client and clearly explains the benefits of notification. This can greatly improve the affected individual's willingness to reveal behaviors and names to an individual the client has just met.

APPENDIX C

Spouse and Partner Notification Activities: State Level Data

Table 2: Barriers to Spousal Notification and State Solutions, continued

Issue	Description	State Solutions
Patients	HIV notification can usually only proceed with the client's consent and cooperation. A client may not be able or willing to discuss partners while digesting HIV test results. Patients may lack information about partners from longer time periods or may refuse to identify spouses due to domestic violence concerns.	Clearly identify notification as a voluntary process. Market spouse and partner notification as a service rather than an imposition. Require post-test counseling to include a discussion of the benefits of notification, a description of the process and an explanation of available services and participation options.

APPENDIX C

Spouse and Partner Notification Activities: State Level Data

Table 3: Data Collection in the 11 Sampled States

Type of Data Collected	States
Number of newly identified index cases eligible for post-test interview	FL MO NJ NC
Number of index cases which result in a notification discussion	FL MO NJ NY NC
Number of index cases which result in spouse or partner elicitation*	FL NJ NC
Number of contact notifications that were spousal notifications	NJ
Number of index cases interviewed within specific time frames	FL NC
Average contact index (average number of contacts elicited per interview)	MO NJ NC
Total number of contacts elicited from all interviews	FL MO NJ NC
Number of elicited partners who were notified within a certain time period	FL NJ NC
Number of elicited partners who were not contacted or notified	FL NJ NC
Disposition of HIV test administered to a notified spouse or partner	FL NJ

Notes:
*This category differs from the previous one in that Missouri and New York monitor whether a notification discussion occurred, not whether contacts were elicited. It can be assumed that if contacts were elicited, a discussion occurred. Thus, some States listed as tracking information in this category are also listed as tracking information in the "Number of cases which result in a notification discussion" category.

Florida - Cases are tracked by "closed" cases only. Cases which do not result in an interview are sorted by reason for lack of interview - "refused interview", "unable to locate" and "other". The State also notes how many contacts are "new" partners. Of the new partners, the interview activity report records how many have had a previous negative HIV test, how many have not been tested and how many refused to be tested.

Missouri - A "new" case is one which has not been previously reported to the State. All newly reported HIV cases are interviewed, unless a physician specifically indicates that the patient should not be contacted. The interview consists of spouse and partner elicitation and referral to HIV care services.

North Carolina - Monthly Epidemiologic Case Reports also track the number of cases which do not result in an elicitation interview and the number of cases with no contacts named. All the information is tracked for HIV cases and AIDS cases. The data is also broken out by gender of the index case.

United States Government Accountability Office

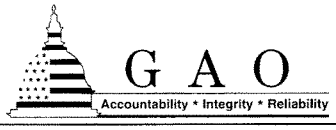
GAO

Report to Congressional Requesters

April 2006

RYAN WHITE CARE ACT

Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs



GAO-06-646

Appendix II: State Approaches to Identifying and Notifying Partners of HIV-Infected Individuals of Possible HIV Exposure

Research suggests that most new HIV infections originate from HIV-infected persons not yet aware of their infection.[1] This emphasizes the need to identify HIV-infected persons and link them with appropriate services as soon as possible. The Ryan White CARE Act Amendments of 1996 provided for states to take action to require a good faith effort be made to notify spouses who may have been exposed to HIV.[2] Partner counseling and referral services (PCRS) assist HIV-infected persons with notifying their partners, including spouses, of their exposure to HIV.[3] This appendix provides information on state approaches to identifying and notifying partners of HIV-infected individuals of possible HIV exposure.

Background

In 1996, legislation amending the CARE Act also prohibited CARE Act grants to any state that did not take administrative or legislative action to require that a good faith effort be made to notify the spouse of an HIV-infected individual that he or she may have been exposed to HIV and should seek testing. CDC, in coordination with the Health Resources and Services Administration (HRSA), took the lead in determining state compliance with the requirement. In December 1996, CDC asked the states to certify compliance with the spousal notification requirement and to submit a summary of additional actions taken or planned for assuring that a good faith effort is made to notify spouses of a known HIV-infected person. Because states had been administering partner notification programs that included spouses for years, particularly programs for syphilis and other sexually transmitted diseases (STD), the actions states certified were both ongoing efforts and additions to their PCRS programs that were designed to specifically address the spousal notification

[1]G. Marks, N. Crepaz, J. W. Senterfitt, and R. S. Janssen, "United States: Meta-Analysis of High-Risk Sexual Behavior in Persons Aware and Unaware They Are Infected with HIV in the United States," *Journal of Acquired Immune Deficiency Syndromes*, vol. 39, no. 4 (2005).

[2]Pub. L. No. 104-146, § 8, 110 Stat. 1346, 1372 (codified at 42 U.S.C. § 300ff-27a (2000)). The statute defines a spouse as "any individual who is the married partner of an HIV-infected patient, or who has been the married partner of that patient at any time within the 10-year period prior to the diagnosis of HIV infection."

[3]CDC's PCRS guidance for HIV defines PCRS as a prevention activity with the goals of (1) providing services to HIV-infected persons and their sex and needle-sharing partners so they can avoid infection or prevent transmission to others, and (2) helping partners gain earlier access to individualized counseling, HIV testing, medical evaluation, treatment, and other prevention services.

requirements. In 1997, CDC approved the certifications of compliance submitted by all states, the District of Columbia, and five territories.[4]

In August 1999, the Department of Health and Human Services' (HHS) Office of Inspector General issued a report on state implementation of their CDC-approved plans for the spousal notification requirement.[5] The HHS Inspector General reported that all 11 sampled states had followed up on the actions reported to and approved by CDC for compliance with the spousal notification requirement. For example, states were revising training materials, revising counseling guidelines, and retraining counselors based on the spousal notification requirement. Also, several states were undertaking promising notification efforts, according to the report. The HHS Inspector General recommended that states make additional efforts to ensure maximum notification while ensuring confidentiality.

States Use Various Approaches to Elicit Information and Notify Partners of Possible HIV Exposure

We contacted 12 states to determine what approaches they use to identify and notify partners of HIV-infected individuals.[6] These 12 states said they use various approaches in conducting HIV partner notification activities as part of their PCRS programs. These activities include eliciting partner information from known HIV-infected individuals—referred to as index cases[7]—and notifying the partners of their possible exposure to the virus. The states use a variety of entities and individuals trained to conduct these activities. Of the 12 states we contacted, 10 have statutory or regulatory provisions that require or permit certain health care entities or workers to notify partners without the consent of the index case. Some states reported integrating their HIV activities with established programs that are focused on syphilis and other STDs.

[4]The five territories included Guam, the Northern Mariana Islands, the Republic of Palau, the Commonwealth of Puerto Rico, and the Virgin Islands.

[5]Department of Health and Human Services Office of Inspector General, *The Ryan White CARE Act: Implementation of the Spousal Notification Requirement* (Washington, D.C.: Department of Health and Human Services, 1999).

[6]The 12 states we contacted were California, Connecticut, Florida, Kentucky, Massachusetts, Minnesota, Missouri, New York, North Carolina, Pennsylvania, Texas, and Washington.

[7]Index case is a generic term for a person who has tested positive for HIV and is asked to name spouses and partners at the start of the notification process.

States Conduct HIV Partner Notification Activities Using a Variety of Trained Workers

Officials from all 12 states we contacted reported having PCRS programs that include eliciting information about the partners of individuals known to be infected with HIV, notifying the partners of their possible exposure to the virus, and providing the partners with counseling and testing services. Officials in all 12 states said that they use public health care workers known as disease intervention specialists for conducting partner notification activities.[8] Four states also use physicians; three states use community-based organizations; one state uses staff at counseling and testing sites; and one state uses staff working in jails to help conduct partner notification activities.

Officials from all 12 states told us that the state provides training for the individuals who conduct partner notification activities for their PCRS programs. These individuals are trained to use various techniques for eliciting information from index cases, their partners, and their social associates, and for notifying partners of their possible exposure to HIV or other communicable diseases. Officials from all 12 states said they provide CDC-developed training and other training for disease intervention specialists.[9] In addition, some state officials said they provide training to other groups that are involved in PCRS. For example, New York officials said that the state department of health conducts PCRS training with a variety of groups, including community-based organizations and staff working in jails, to improve their skills in eliciting information about partners. Massachusetts officials told us that they were training community-based organization staff in how to elicit partner information and notify exposed partners in an effort to integrate them into prevention services, and California officials said that they were training staff working at community-based organizations and disease counseling and testing sites.

[8]Disease intervention specialists interview patients, at-risk individuals, and those infected with STDs (including HIV), and ensure appropriate examination, treatment, and follow-up to persons exposed or infected with an STD. Pennsylvania uses its field staff to perform duties similar to those of disease intervention specialists in other states. In this report, we refer to these Pennsylvania field staff as disease intervention specialists.

[9]CDC training includes courses such as Introduction to STD Intervention, Fundamentals of STD Intervention, and HIV Partner Counseling and Referral Services.

States Primarily Use Interviews to Identify Partners and Various Methods to Notify Them of Their Possible Exposure to HIV

Generally, all 12 states use similar methods to obtain identifying information about partners of persons known to be infected with HIV and notifying the partners of their possible exposure to the virus. The states elicit information about HIV-exposed partners primarily through interviewing the index cases about their direct sex and needle-sharing partners. Some states also use interviews and a technique called clustering to identify social associates of the index case that may be at risk of exposure to HIV. In clustering, states may try to obtain information about things such as buildings where drug use occurs or other venues frequented by HIV-infected individuals. Because participation in PCRS is voluntary, some index cases may opt not to participate and may not provide information about their partners and other contacts. For example, New York officials we contacted said that the proportion of HIV index cases that do not provide partner identifying information is quite high. They do not know what percent of index cases refuse to divulge the information versus the health care provider's failure to ask or record the information. In 2003, New York City health care providers submitted 5,213 reports to the city's HIV Epidemiology Program that were completed on patients with a new diagnosis of HIV. Seventy-five percent of the reports did not list a partner of the newly diagnosed HIV-positive patients.

Once partners are identified, states primarily use three CDC-suggested methods to notify them of their possible exposure to HIV.[10] These methods are (1) client self-referral, in which index cases notify partners, (2) contract referral, in which a time frame is negotiated and agreed to with index cases for them to notify partners, and (3) provider referral, in which the health care provider or health department conducts the follow-up with partners.

In all 12 states we contacted, index cases retain the option of notifying their partners that they have exposed them to HIV. Although they have this option, index cases may prefer to receive assistance from individuals trained in partner notification. For example, North Carolina officials said that most index cases prefer to have trained disease intervention specialists do the notification on their behalf because of concerns with confronting their partners about their HIV infection and having exposed them to the virus. When index cases opt to notify their partners, it is

[10]Centers for Disease Control and Prevention, *Program Operations Guidelines for STD Prevention: Partner Services* (Atlanta, Ga.: Centers for Disease Control and Prevention, 2001).

difficult for the health department to track whether partners indeed have been notified. Eight of the 12 states negotiate agreements with index cases that include, for example, that index cases will notify their partners by a certain date or the state may notify the partners. In Connecticut, such agreements are in writing and outline how partners will be informed, how it will be confirmed that partners were notified, and what follow-up is required when partner counseling and referral services are not provided.

In all 12 states, health care providers or workers may notify partners. With this CDC-suggested method, index cases request provider assistance with partner notification and may give the provider identifying information such as addresses and phone numbers to follow-up with their partners. Research suggests that the use of health care providers or workers is more effective than the index cases notifying partners of their possible exposure to HIV.[11]

Of the 12 states we contacted that conduct partner notifications, 10 have statutory or regulatory provisions that require or permit certain health care workers or entities, such as physicians and health departments, to notify partners, including spouses, of their possible exposure to HIV without the consent of the index case.[12] In New York, North Carolina, and Texas, statutory or regulatory provisions require that public health officials or health departments notify partners, including spouses,[13] of their possible exposure to HIV. In California, Connecticut, Florida, Kentucky, Missouri, New York, Pennsylvania, and Washington the provisions permit health care providers, public health officials, or health departments to notify partners, including spouses, of their possible exposure to HIV.[14] In California where physicians are permitted to notify partners, a California

[11]Suzanne E. Landis et al., "Results of a Randomized Trial of Partner Notification in Cases of HIV Infection in North Carolina," *The New England Journal of Medicine*, vol. 326, no. 2, 101-106 (1992). Beth A. Macke and Julie E. Maher, "Partner Notification in the United States: An Evidence-Based Review," *American Journal of Preventive Medicine*, vol. 17, no. 3, 230-242, (1999).

[12]In some of these states, physicians or health departments may notify partners only when certain conditions are met, such as when the index case has been advised to notify partners but refuses. Some states have provisions also permitting parties other than health care providers or health departments to notify partners.

[13]The North Carolina provision applies only to notification of spouses; state officials told us that they generally notify partners with the consent of the index case.

[14]One New York provision requires public health officials to notify partners; another permits physicians to notify partners.

official told us that the health department is trying to get physicians more involved in partner notification but said that generally physicians do not have the time or staff to conduct the notifications. In the remaining 2 states—Massachusetts and Minnesota—public health officials or health departments may notify partners, including spouses, only with the consent of the index case. Moreover, Massachusetts has an HIV-specific confidentiality provision that explicitly prohibits health care providers and facilities from disclosing an individual's name or HIV test results without the individual's written informed consent. Massachusetts officials said that they believe the number of partners notified is lower in states with strict confidentiality laws compared to states without strict laws.

Some states use the Internet as a tool for contacting and notifying partners of known HIV-infected individuals. A California official told us that the Internet provides a new opportunity to facilitate partner notification. Officials from Minnesota, Missouri, Pennsylvania, and Texas said they obtain information, such as Web site addresses and associated chat rooms that partners use, partners' screen names, and e-mail addresses, from index cases and use the Internet to initiate contact and send messages to partners. Officials from three states expressed concern about using the Internet and visiting certain Web sites to contact partners because of confidentiality concerns or provisions that prohibit employees from visiting sexually-oriented sites. The extent to which states use the Internet for HIV partner notification varies. For example, Kentucky, New York, and Washington State officials said that their use of the Internet is limited to certain geographic areas within the state.

After partners are contacted and notified about their possible exposure to HIV, they are usually counseled about HIV and offered testing. CDC guidelines state that counseling should consist of providing a description of the ways in which HIV is transmitted, the importance of obtaining test results, the meaning of HIV test results, and ways to prevent future exposure to HIV. Officials from all 12 states we contacted said that disease intervention specialists that notify partners of their possible exposure to a communicable disease encourage them to get tested. Officials from these states said that when partners have been exposed to more than one communicable disease, such as syphilis and HIV, they will encourage partners to get tested for both diseases. Officials in California and Connecticut told us that when index cases are co-infected and want health department assistance with informing their partners about possible exposure to syphilis but not HIV, the partners will not be told about their exposure to HIV. Instead, the partners may be told that the risk behavior

that exposed them to syphilis may have also exposed them to HIV and that getting tested for both is recommended.

The participation of HIV index cases and partners in PCRS program activities varies among the states. As previously mentioned, participation in state PCRS is voluntary. New York officials told us that the number of index cases that do not provide partner identifying information is quite high, but they do not know what percentage of index cases refuse to divulge this information. Pennsylvania Department of Health officials told us that in 2004, there were over 300 HIV-positive cases in the state, and that 89, or less than one-third, used PCRS. A California state official told us that because the state does not use name-based reporting of individuals diagnosed with HIV, the state is not able to track those who received partner services and how many actually got tested. PCRS data collected by CDC show wide variability in elicitation and notification activities among states. Among 10 of the 12 states in our review,[15] CDC data for 2002 show that the percentage of index cases interviewed for PCRS ranged from about 46 percent to 100 percent. Similarly, the percentage of partners elicited who were located and notified ranged from about 42 percent to 83 percent. Among partners who were located and notified, about 89 percent received counseling, and approximately 90 percent of partners who were counseled were then tested for HIV.

Seven States Have Integrated HIV and STD Partner Notification Activities and Training

Health officials from 7 of the 12 states we contacted said they have combined certain activities in their HIV and STD programs to facilitate partner notification. In these 7 states, staff that conduct partner notification are trained in notifying partners of their exposure to HIV and other STDs. For example, Texas state public health officials said that their PCRS program integrates HIV and STD activities. They said a large percentage of their HIV cases are also infected with syphilis, and disease intervention specialists that are trained in all STDs can notify partners of their exposure regardless of the disease. In Texas, local health departments that have separate HIV and STD units have been encouraged to consolidate their efforts. Florida officials said that information from a syphilis outbreak among men who have sex with men shows that in 2004, 28 percent of these men were infected with HIV at the time they were

[15]CDC's 2002 PCRS data did not include data from Massachusetts and Missouri. CDC told us that Massachusetts did not use its CDC HIV prevention funds for PCRS so it was not required to report PCRS data. Missouri's data did not pass CDC's reliability tests.

diagnosed with syphilis. These officials said that from a resource standpoint, it does not make sense to have one person notify partners about their exposure to HIV and another person notify them about syphilis. Florida maximizes its resources by using the same staff to conduct all STD notifications. North Carolina health officials told us that their HIV and STD programs are totally integrated because it is hard to separate HIV and STD prevention efforts. North Carolina disease intervention specialists are trained in all STDs and can notify partners of their exposure to HIV and other STDs. Washington officials said that some, but not all, of their STD and HIV programs are integrated. In some jurisdictions the programs are divided while in others the staff is shared. They said that small health departments are more integrated because they cannot afford to have separate staff doing partner notification for the different diseases.

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May 22, 2006

Daniel R. Levinson
Inspector General
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Dear Mr. Levinson,

Thank you for your continued efforts to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs. I appreciate the dedication of you and your staff towards these ends.

Ten years ago, Congress passed and President Clinton signed Public Law 104-146 that would require, as a condition of state eligibility for federal Ryan White CARE Act funds, "a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to HIV and should seek testing."

In explaining the provision when offered as an amendment in the U.S. Senate, the author—then-Senator Jesse Helms-- stated that the intent was to ensure that "States are going to have to make a genuine and concerted effort" to ensure that spouses are "promptly notified" of possible HIV exposure by a current or previous spouse (pages S10708 - S10709 of the *Congressional Record* for July 26, 1995). The amendment was overwhelming approved 98 to zero by the U.S. Senate and unanimously by the members of the House/Senate conference of which I was a member.

As a practicing physician who has cared for a number of patients living with HIV/AIDS, I believe that confidential notification is a necessary and effective public health strategy that helps break the chain of transmission by alerting those at risk before they become infected and to ensure lifesaving treatment and secondary prevention to those who have already been infected. This is especially important for spouses who have no reason to suspect that they are at risk and therefore are unlikely to take any precautions to guard them against infection or to seek testing that could diagnose their condition and ensure access to treatment when it is most effective. There have been countless stories of women and men who became unknowingly infected by a partner or spouse who hid his or her status and the spouse only learned of the infection when diagnosed with an AIDS-defining illness, far too late to maximize the benefits of existing medical therapies or prevent perinatal transmission to their children. The 1996 spousal notification law was intended to end tragedies such as these.

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But that has not been the case because the law appears to never have been fully enacted.

In a letter dated January 26, 1998, then-Secretary of Health and Human Services Secretary Donna E. Shalala stated that the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) jointly coordinated the implementation of this provision that went into effect April 1, 1997.

According to Secretary Shalala's letter, "examples of program principles and practices that CDC believes would minimally constitute a good-faith effort regarding HIV spousal notification were developed by CDC and HRSA in consultation with health department and community representatives and were provided to the States in their certification packages. These included the following:

"For individuals reported to the State on or after April 1, 1997, as being diagnosed with AIDS (or HIV infection in States requiring HIV-infection reporting by law or regulation), if not already determined by the reporting health care provider, each such individual shall be:

-- asked if he or she has, or has had, a spouse (defined by this law as "any individual who is the marriage partner of an HIV-infected patient or who has been the marriage partner of an HIV-infected patient at any time within the 10-year period prior to diagnosis of HIV infection");

-- informed that he or she should notify his or her spouse, or former spouses, of the potential exposure to HIV.

"Reasonable efforts must be made to determine if each HIV-infected individual intends to notify his or her spouse of their possible exposure to HIV or agrees to have a qualified health care provider notify them. In situations where the HIV-infected individual reports that he or she intends to notify the spouse, culturally competent counseling and educational services on the following issues should be available:

-- how to make the notification;

-- how to preserve confidentiality of both the individual and the spouse;

-- how HIV infection and transmission can be prevented;

-- how the spouse can access testing, other prevention services, and treatment.

"If the HIV infected individual is unable or unwilling to notify his or her spouse, culturally competent services should be available from the provider or the health department to do so."

Secretary Shalala's letter further states, "Unless covered by existing law, policy, or regulation, States should develop policies that address situations involving HIV-infected individuals who do not plan to notify their spouses and who refuse health department assistance."

But the letter notes "CDC and HRSA agreed that appropriate State health agency officials should have the authority to define a 'good faith effort' for their jurisdictions" and that "as of February 1, 1997, CDC and HRSA had determined that all 50 states were essentially in compliance with Public Law 104-146."

In essence, HHS and the agencies abdicated their responsibilities to enforce the law and allowed states to "rubber stamp" their own compliance.

In three follow-up letters between March and June 1998 to Secretary Shalala, I forwarded reported evidence in three separate states—New York, New Jersey and California—that spousal notification was being hindered by state laws and regulations.

On June 25, 1998, Congressman Tom Bliley, the chairman of the U.S. House Committee on Commerce wrote to Secretary Shalala stating that "the Committee is becoming increasingly concerned that States are falling considerably short of complying with" the spousal notification law.

On July 9, 1998, Secretary Shalala responded that "The Centers for Disease Control and Prevention (CDC) requires documentation that every state health official has certified that a good faith effort will be made to comply with the provisions of Public Law 104-146" and that "CDC relies on its State partners to ensure that materials submitted to CDC are accurate." As noted previously, CDC allowed states to self-certify their own compliance.

When pushed for additional evidence that spouses were in fact being notified of potential HIV-exposure, Dr. Claire V. Broome, Acting Director of the CDC responded in a letter dated September 17, 1998, that "State and local health departments do not have reporting systems in place that provide information on the number of spouses notified. Similarly, there is no national system for collecting comprehensive data on the number of spouses or other partners of HIV-infected individuals who are notified of their potential exposure to HIV."

On October 1, 1998, I sent a letter to then-Inspector General (IG) June Gibbs Brown to "request that the OIG conduct an investigation to determine if States are indeed conducting federal spousal notification as required under the Ryan White CARE Act Amendments of 1996."

In a letter dated May 28, 1999, the IG stated that "there is little hard data to document the results of States' notification efforts." The IG's final report was released in August 1999, noting that "While States have taken action on their certifications, their efforts do not completely ensure that vulnerable people are always made aware of their

possible exposure to HIV. Based on our findings, additional efforts need to be undertaken to ensure maximum notification while ensuring confidentiality and meeting patients' needs."

Last month, the Government Accountability Office (GAO) released a report analyzing the laws and policies of twelve states that found continuing shortcomings with state compliance of the federal spousal notification law.

According to GAO, "In New York, North Carolina, and Texas, statutory or regulatory provisions require that public health officials or health departments notify partners, including spouses, of their possible exposure to HIV." This is the intent of the federal law.

However, GAO found that "In California, Connecticut, Florida, Kentucky, Missouri, New York, Pennsylvania, and Washington, the provisions permit health care providers, public health officials, or health departments to notify partners, including spouses, of their possible exposure to HIV." This approach falls short of the legal requirement. The law states that HHS shall not make a grant to any State "unless such State takes administrative or legislative action to require that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to HIV." The verb in the law is "require," not "permit."

Furthermore, GAO found that "In the remaining 2 states—Massachusetts and Minnesota—public health officials or health departments may notify partners, including spouses, only with the consent of index patient." This is an overt violation of the federal law.

In summary, an analysis of twelve states' laws by GAO sound only three which appear to be complying with the federal condition for CARE Act funding yet all have been certified by CDC as being compliant.

CDC staff dispute the GAO's findings and claim that States are indeed complying with the federal law by making "good faith" efforts to notify spouses of HIV-infected individuals.

The dubious nature in which States' compliance were certified and the repeated findings by Congress, the HHS OIG, and GAO that States were not complying with the law raise serious and lingering questions.

I request that the OIG conduct a thorough review of any actions the CDC and States took since the OIG issued its findings and recommendations in 1999 and an analysis of all State spousal notification laws to ensure that every State receiving funding under the Ryan White CARE Act is, in fact, complying with this federal law requiring notification of spouses of HIV-infected individuals as a condition of funding.

Additionally, I would request a separate examination of laws, in addition to the spousal notification law, that HHS and its agencies have allowed grantees to interpret and self-certify their own compliance. This practice is very worrisome because it may result in confusion, uncertainty, federal laws not being properly enacted or enforced, or the denial of rights and responsibilities. Lawmakers need to be assured that there is sufficient accountability and transparency of the laws we pass.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Tom A. Coburn, M.D.
Chairman
Subcommittee on Federal Financial Management,
Government Information, & International Security

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Enclosures

Appendix 1

Public Law 104-146

SPOUSAL NOTIFICATION.

(a) IN GENERAL.--The Secretary of Health and Human Services shall not make a grant under part B of title XXVI of the Public Health Service Act (42 U.S.C. 300ff-21 et. seq.) to any State unless such State takes administrative or legislative action to require that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to HIV and should seek testing.

(b) DEFINITIONS.--For purposes of this section:

(1) SPOUSE.--The term 'spouse' means any individual who is the marriage partner of an HIV-infected patient, or who has been the marriage partner of that patient at any time within the 10 year period prior to the diagnosis of HIV infection.

(2) HIV-INFECTED PATIENT.--The term 'HIV-infected patient' means any individual who has been diagnosed to be infected with the human immunodeficiency virus.

(3) STATE.--The term 'State' means any of the 50 States, the District of Columbia, or any territory of the United States.

Appendix 2

Congressional Record
Senate - July 26, 1995
S10708 - S10709

AMENDMENT NO. 1853
(PURPOSE: TO REQUIRE SPOUSAL NOTIFICATION IN CASES IN WHICH AN INDIVIDUAL IS DIAGNOSED WITH INFECTION WITH THE HUMAN IMMUNODEFICIENCY VIRUS)

Mr. HELMS. Mr. President, I have some amendments to come before the Senate. I do not intend to second-degree anybody else's amendment, and I hope we can just have up-and-down votes and get this bill out of the way.
Now, Mr. President, I send an amendment to the desk and ask it be stated.

The PRESIDING OFFICER. The clerk will report.
The legislative clerk read as follows:
The Senator from North Carolina [Mr. Helms] proposes an amendment numbered 1853.

Mr. HELMS. Mr. President, I ask unanimous consent that further reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.
The amendment is as follows:
At the end, add the following new section:
SEC. . SPOUSAL NOTIFICATION.
(a) Prohibition on the Use of Funds: The Secretary shall not make a grant under this Act to any State or political subdivision of any State, nor shall any other funds made available under this Act, be obligated or expended in any State unless such State takes administrative or legislative action to require that a good faith effort shall be made to notify a spouse of an AIDS-infected patient that such AIDS-infected patient is infected with the human immunodeficiency virus.
(b) Definitions: As used in this section--
(1) AIDS-Infected Patient: The term `AIDS-infected patient' means any person who has been diagnosed by a physician or surgeon practicing medicine in such State to be infected with the human immunodeficiency virus.
(2) State: The term `State' means a State, the District of Columbia, or any territory of the United States.
(3) Spouse: The term `spouse' means a person who is or at any time since December 31, 1976, has been the marriage partner of a person diagnosed as an AIDS-infected patient.
(c) Effective Date: Subsection (a) shall take effect with respect to a State on January 1 of the calendar year following the first regular session of the legislative body of such State that is convened following the date of enactment of this section.

Mr. HELMS. Let me sum up this amendment. I think we had two votes against it the last time. This amendment requires that States receiving Federal funds for AIDS education and prevention take specific legislative and/or administrative steps to make sure that spouses--that is, the wife or husband--of an individual infected with the HIV/AIDS virus, that the spouse be promptly notified.

Let me say why I think we ought to vote on this again. Some years back, 2 or 3, I forget how long ago, there were several circumstances that led me to draft this amendment at that time.
It began when I received a call from a young woman who worked on the House side of the Congress who said, `Senator, my mother wants to come by and talk with you on a matter of confidence. She doesn't want you to ever use her name,' and I shall not. They came, a lovely lady and her beautiful daughter. I shall never forget that visit. The meeting did not last long. After the usual amenities--and I had no idea what the lady wanted to discuss--but after the usual amenities, I seated them. The three of us began to discuss why she had come and what I might be helpful to her about.
At that point, tears welled up if that mother's eyes as she began to tell the story. She took a deep breath and stated the bottom line. She had AIDS, she said, `and I am dying.' Her bisexual husband, you see, had infected her with the AIDS virus. He had not informed her he was infected, and State law in her State forbade the family doctor from telling her--which I consider to be outrageous.
Now, Mr. President, we hear so much about protecting the confidentiality of AIDS-infected patients, yet we hear nothing about the fatal consequences of confidentiality laws. The homosexuals march in Washington, and they demand their rights, but what about the rights of this lovely lady and the thousands of others like her, potentially, who, through no fault of their own, have become infected with the deadly AIDS virus, or may be infected in the future?
Do they not have rights, too? Should there not be laws to protect the innocent spouses, instead of those who hide behind the confidentiality law and, as in this case, are causing others to die?
What a terrible tragedy. Only 12 States protect the lives of spouses of HIV-infected citizens, only 12 States. Eighteen States provide for notification of partners, but they are silent on the rights of spouses. What kind of fair play is that? And you know what I mean when I say `partner.'
Does this not lead to the conclusion that some States may appear more concerned with protecting the interests of the HIV-positive spouse instead of the life of the unsuspecting innocent spouse?
This amendment does not require States to initiate a spousal notification program. It simply says that if States want Federal money, which they take from the taxpayer--if States want money to combat the AIDS virus, the AIDS disease, those States are going to have to make a genuine and concerted effort to protect innocent spouses from being exposed to the AIDS virus.
It is time to start treating AIDS as the public health issue that it is, rather than the civil rights issue that it has become. I have no doubt that if we take this step, it will help curb, to some extent at least, the spread of this lethal disease.

Mrs. KASSEBAUM addressed the Chair.

The PRESIDING OFFICER. The Senator from Kansas.

Mrs. KASSEBAUM. Mr. President, maybe, as a clarification of what we did last year, it is my understanding that, in law, from what we had before, that each State is required to set up its own notification system. Is that correct?

Mr. HELMS. Not to my knowledge. But even if it is, if you will forgive me, it will not hurt the Senate to go on record again.

Mrs. KASSEBAUM. No, I have no problem--I was just asking the Senator if he knew if that was not correct that each State is required to set up its own?

Mr. HELMS. My expert is sitting to my left, and sometimes to my right as well, and she says she does not know about that. And so, of course, I do not.

Mrs. KASSEBAUM. Mr. President, I suggest the absence of a quorum for a minute until we look at the language and get some comparison, so maybe we can accept that.

Mr. HELMS. That is fine, just so there is no attempt to second-degree my amendment, because then we will have protracted debate.

Mrs. KASSEBAUM. No, I agree with the Senator. I know the effect of a second-degree amendment.

Mr. HELMS. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.
The legislative clerk proceeded to call the roll.

Mr. HELMS. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. Thompson). Without objection, it is so ordered.

Mr. HELMS. Mr. President, I ask for the yeas and nays on the pending amendment.

The PRESIDING OFFICER. Is there a sufficient second?
There is a sufficient second.
The yeas and nays were ordered.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I hope that this amendment will be accepted by the membership. I intend to vote for it.

The PRESIDING OFFICER. Is there further debate on the amendment? If not, the question is on agreeing to the amendment. On this question, the yeas and nays have been ordered, and the clerk will call the roll.
The legislative clerk called the roll.

Mr. LOTT. I announce that the Senator from Utah [Mr. Bennett], is necessarily absent.

Mr. FORD. I announce that the Senator from Illinois [Mr. Simon], is necessarily absent.

The PRESIDING OFFICER. Are there any other Senators in the Chamber who desire to vote?
The result was announced--yeas 98, nays 0, as follows:

Rollcall Vote No. 332 Leg.

[Rollcall Vote No. 332 Leg.]

YEAS—98

- Abraham
- Akaka

- Ashcroft
- Baucus
- Biden
- Bingaman
- Bond
- Boxer
- Bradley
- Breaux
- Brown
- Bryan
- Bumpers
- Burns
- Byrd
- Campbell
- Chafee
- Coats
- Cochran
- Cohen
- Conrad
- Coverdell
- Craig
- D'Amato
- Daschle
- DeWine
- Dodd
- Dole
- Domenici
- Dorgan
- Exon
- Faircloth
- Feingold
- Feinstein
- Ford
- Frist
- Glenn
- Gorton
- Graham
- Gramm
- Grams
- Grassley
- Gregg
- Harkin
- Hatch
- Hatfield
- Heflin
- Helms
- Hollings
- Hutchison
- Inhofe
- Inouye
- Jeffords

- Johnston
- Kassebaum
- Kempthorne
- Kennedy
- Kerrey
- Kerry
- Kohl
- Kyl
- Lautenberg
- Leahy
- Levin
- Lieberman
- Lott
- Lugar
- Mack
- McCain
- McConnell
- Mikulski
- Moseley-Braun
- Moynihan
- Murkowski
- Murray
- Nickles
- Nunn
- Packwood
- Pell
- Pressler
- Pryor
- Reid
- Robb
- Rockefeller
- Roth
- Santorum
- Sarbanes
- Shelby
- Simpson
- Smith
- Snowe
- Specter
- Stevens
- Thomas
- Thompson
- Thurmond
- Warner
- Wellstone

NOT VOTING--2

- Bennett
- Simon

So the amendment (No. 1853) was agreed to.

How Newborn Testing is Eliminating Baby AIDS

In 1994 it was discovered that administering the AIDS drug zidovudine (ZDV, also known as AZT) to pregnant women and newborns can dramatically reduce the risk of perinatal HIV transmission. Yet despite this miraculous scientific discovery, hundreds of babies continue to be infected with HIV in the U.S. every year because neither they nor their mothers are tested for HIV-antibodies and, as a result, denied the treatment that can prevent infection.

At the time this discovery was made, the Centers for Disease Control and Prevention (CDC) had been conducting a seroprevalence survey to determine the number of pregnant women infected with HIV that involved testing nearly every newborn delivered in the U.S. for HIV. The CDC survey withheld the HIV status from the mother. Rather than disclose the test results that could potentially save hundreds of babies from HIV and link infected mothers to treatment, CDC discontinued the survey in 1995 and joined with AIDS activists in opposing Congressional and state legislative proposals to enact routine testing of pregnant women and universal testing of newborns. As a result thousands of babies have been born to HIV-infected mothers over the past decade and denied life saving treatment.

Despite the opposition of the CDC and AIDS activists some states enacted laws requiring routine testing of pregnant women (with the right to opt out of such testing), universal newborn testing, or testing of newborns whose mothers' HIV status was unknown. These states have experienced dramatic reductions in perinatal HIV transmission. Connecticut has virtually eliminated perinatal HIV transmission and New York—with the nation's highest HIV/AIDS caseload—has identified every newborn as risk and linked the children and their mothers to treatment.

In 2003, based in part of the success of these states and the continued infection of hundreds of babies a year, CDC issued new recommendations for routine HIV testing of all pregnant women, and, as a safety net, testing of any infant whose mother was not screened.

This section contains additional background on this issue including information on successful state "baby AIDS" laws and the arguments made for and against newborn testing.

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perspectives children's AIDS fund

Baby AIDS

Roland R. Foster

Foreward

Perhaps the single, most significant achievement in the battle against HIV/AIDS has been the discovery of medical interventions to nearly eliminate perinatal HIV transmission. Beginning with the 1994 announcement of the AIDS Clinical Trials Group protocol number ACTG 076 (076) that found the use of the AIDS medication zidovudine (ZDV) could dramatically reduce the transmission of HIV from an infected mother to her child, science has made it possible that extremely few babies will ever have to be born with HIV desease. Yet despite this promise, hundreds of babies continue to be infected with HIV every year in the United States. This raises some very important questions. Why is it that so many babies are allowed to have their lives cut short and die from AIDS when perinatal HIV infection can nearly be entirely prevented? What policies could have been – and should be – put in place to take advantage of the medical miracle that is available to save babies from AIDS?

Women and Children Increasingly Impacted by HIV

By the end of 1999, nearly 8,000 perinatally acquired AIDS cases had been recorded in the U.S., the vast majority (84 percent) of which are black and Hispanic children.[1] Most of the AIDS cases resulting from children born with HIV infection since 1997, however, have yet to be diagnosed or reported.[2] An estimated 120,000 to

Perhaps the single, most significant achievement in the battle against HIV/AIDS has been the discovery of medical interventions to nearly eliminate perinatal HIV transmission.

160,000 HIV-infected women are living in the United States, 80 percent of whom are of childbearing age.[3] Approximately 6,000 to 7,000 HIV-infected women gave birth in the U.S. each

year from 1985 to 1995.[4] And as women continue to comprise an increasing proportion of new HIV cases, more and more children are likely to be affected by the disease if no positive action is taken. Likewise more of the children and their mothers continue to disproportionately represent communities of color. African American and Hispanic women accounted for 80 percent of AIDS cases reported in U.S. women in 1999.[5]

During the early 1990s, before perinatal preventative treatments were available, an estimated 1,000 to 2,000 infants were born with HIV infection each year in the United States.[6] The incidence of perinatally acquired AIDS peaked in 1992, and dramatically declined in the aftermath of the 076 study and the subsequent Public Health Service (PHS) recommendations made in 1994 and 1995 for routinely counseling and voluntarily testing pregnant women for HIV, and for offering ZDV to infected women and their infants.[7] Without intervention, the mother-to-infant transmission rate would result in the birth of an estimated 1,750 HIV-infected infants annually in the U.S.[8] Today – despite the fact that perinatal transmission can be nearly eliminated – the Centers for Disease Control and Prevention estimates that 300- 400 babies continue to be born with HIV infection each year in the United States.[9]

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Many Women are Still Not Tested, and Thereby Denied Care for Their Children and Themselves

In response to 076, the Centers for Disease Control and Prevention issued recommendations more than a year later, in 1995, requiring all healthcare providers to counsel pregnant women about HIV and offer voluntary testing with informed consent. The CDC released revised draft recommendations for HIV screening for pregnant women in October 2000 that vary slightly, but maintain the emphasis of the 1994 recommendations. No other prenatal medical screening for any other condition required such extensive pre-test criteria to be performed. Studies and anecdotal reports have found that this "AIDS exceptionalist" approach to perinatal HIV prevention has hindered efforts to effectively identify all affected women and newborns. There is a patchwork of different approaches and results in the various states.

Most HIV-infected pregnant women are still not tested and remain undiagnosed according to the findings of a study that examined a voluntary prenatal HIV testing program in northern California. The voluntary approach only resulted in the diagnosis of 20 percent of the HIV-positive pregnancies between 1994 and 1998. "Our experience," concludes Dr. Edgar J. Schoen and colleagues from Kaiser Permanente Medical Care

Program in Oakland, "confirms the desirability of not depending on voluntary prenatal HIV testing to prevent maternal-fetal HIV transmission."[10]

One in five (19 percent) HIV-positive women were not diagnosed before giving birth in 1996 according to CDC data from studies conducted in Louisiana, Michigan, New Jersey and South Carolina.[11]

A state law adopted by Indiana in 1997, requiring all physicians to counsel and offer every pregnant woman an HIV test, has had little impact with less than half receiving HIV tests.[12] Dr. Martin Kleiman, director of pediatric infectious diseases at the Indiana University School of Medicine said that despite the law, for half of the babies who enter Riley Hospital for Children, there is no record of whether the mother has been tested for HIV.[13]

Tennessee, likewise, enacted a law in 1998, requiring all pregnant women be offered HIV tests. Last year, however, there were roughly 70,000 births statewide, but doctors notified the state of offering HIV tests to only 9,314 women during the first nine months. Of the roughly 15,000 births in Shelby County, Tennessee, doctors reported offering tests to only 1,248 pregnant women.[14]

Only 38 percent of pregnant women enrolled by Anthem Blue Cross and Blue Shield in Kentucky received prenatal HIV testing in the state in 1998, even though the cost of the test is covered by the insurer.[15]

"The median percentage of prenatal patients screened for HIV was only 10 percent," according to a study in Minnesota. Just 43 percent of physicians routinely recommended universal HIV screening for prenatal patients according to the researchers.[16]

Only a third of obstetric practices in Vermont and New Hampshire report testing 95 percent of their pregnant patients for HIV. Thirty-seven percent of these practices had HIV testing rates no higher than 50 percent.[17]

> *"the number of children born with HIV, . . . continues to be far above what is potentially achievable" . . .*

Due to barriers and misperceptions, about 30 percent of women are not tested during pregnancy, according to a study published in the May 2001 issue of the *American Journal of Public Health*. "This study suggests that the U.S. health care system is falling short," according to the authors who note "it supports the need to increase HIV testing if HIV infection is to be eliminated among U.S. children."[18]

In Virginia, over 4,000 pregnant women receiving prenatal care in public health clinics did not receive an HIV test in 1997. This is more than one quarter of the 15,160 who received care in Virginia's 32 health districts.[19]

One in five, or about 2,030, pregnant women in Delaware are not tested for HIV during pregnancy according to Dr. Ulder J. Tillman, the Director of Delaware's Health and Services.[20]

More than one in four (28 percent) pregnant women were not tested for HIV in inner city Chicago. Practitioners did not document whether testing was offered in almost 20 percent of the women. Of those women who were screened, 3.5 percent tested positive for HIV.[21]

Likewise, more than one in four pregnant women (28 percent) were not tested for HIV in a study conducted in San Francisco. Sixty-nine percent of patients, however, said that prenatal testing should be routine. The researchers conclude "proponents of elective testing should re-evaluate the assumption that patients view HIV testing differently from other prenatal tests for which separate written consent is not required."[22]

"This study suggests that the U.S. health care system is falling short ... it supports the need to increase HIV testing if HIV infection is to be eliminated among U.S. children."

According to these studies and anecdotes, between 26 and 62 percent of pregnant women are not being tested for HIV. Most alarmingly, depending which state one looks at, 12 to 80 percent of pregnant women who are HIV-positive are not tested, and therefore go undiagnosed and untreated. This increases the number of children who will become infected during or after birth. The CDC has conceded "the birth of every HIV-infected child is a sentinel health event signaling a missed prevention opportunity."[23] Clearly, far too many women and infants are being denied optimal medical care under the CDC's own recommended approach.

The Institute of Medicine (IOM) has echoed this observation, stating "the number of children born with HIV, however, continues to be far above what is potentially achievable," and "more children than necessary continue to be born with HIV infection."[24]

What Approach Will Save Mothers and Babies?

Few would argue today that relying on voluntary prenatal HIV testing is the answer. This approach has not been an effective policy to identify all women and children who need medical intervention and, therefore, has failed to maximize prevention opportunities.

Of the 449 children identified with perinatally acquired AIDS born in 1995-1997, 35 percent had mothers who were not tested for HIV before birth.[25] Roughly 15 percent of HIV-infected pregnant women receive no prenatal care.[26] And only 47 percent of women with HIV receive "adequate" prenatal care according to researchers.[27]

"Newborn children are routinely tested for errors of inborn metabolism and other problems. Although most of the outcomes are rare, a positive test result triggers interventions that benefit both mother and child, and these efforts have been responsible for substantial improvements in health and well-being," according to the IOM. Furthermore, "these tests are well accepted, and seen to clearly benefit the women and her child."[28]

The IOM outlines five criteria that must be met before newborns are screened for a disease. The disease must be both well defined and severe enough to justify screening in large numbers; the cost of the test must be reasonable; an accurate method of testing must exist; treatment must be available; and medical management facilities capable of confirming diagnosis and providing treatment must exist. Application of these five criteria to HIV leads to a conclusion that universal HIV screening for newborns is justified.[29]

Every state requires newborns to be tested for a number of diseases and conditions. All states have mandatory newborn screening for phenylketonuria (PKU) and hypothyroidism. Most also routinely test for galactosemia, and 41 test for sickle cell disease.[30] None of these are as prevalent or deadly as HIV. Yet only two states—New York and Connecticut—require newborns to be screened for HIV. It would seem logical that babies should also be screened for HIV, particularly if the serostatus of a mother is unknown.

Has Routine HIV Testing Been Successful?

Since February 1997, New York has required HIV testing of all newborns. "Universal newborn HIV testing has resulted in the identification of all HIV-exposed births" in the state according to Dr. Guthrie S. Birkhead, Director of the New York Health Department's AIDS Institute. Furthermore, "newborn testing has allowed hospital and health department staff to ensure that over 98 percent of HIV positive mothers are aware of their HIV status and have their newborn referred for early diagnosis and care of HIV infection. In less than two percent of cases have women not been located to receive newborn HIV test results and have their HIV-exposed newborns tested for HIV infection," according to Dr. Birkhead.[31]

Just under 1,000 HIV-infected New York women gave birth in 1998. Approximately 16 percent of these women did not receive prenatal HIV counseling and testing. Therefore, between 100-160 women may be learning their HIV status for the first time from testing conducted in the delivery setting.

. . . depending which state one looks at, 12 to 80 percent of pregnant women who are HIV-positive are not tested, and therefore go undiagnosed and untreated.

In October 1999, Connecticut enacted a Baby AIDS law requiring universal HIV screening of all pregnant women and newborn HIV testing if no documented HIV test is on file for a woman before delivery.

Two studies presented at the 2001 annual meeting of the American College of Obstetricians and Gynecologists proclaimed the law a success.

Dr. Urania Magriples of Yale University in New Haven, Connecticut, said that since the law was enacted, a much greater percentage of women coming to Yale's high risk pregnancy clinic are getting tested for HIV. Before the law, "only 38.9

percent of [pregnant] women were tested for HIV, but after the law 91 percent of women were tested," she said. "I was originally opposed to this law because I thought it was coercion, but it works," Magriples conceded. The law, she explains, actually "appeals to the maternal instincts in these women to protect their babies."

"The birth of every HIV-infected child is a sentinel health event signaling a missed prevention opportunity."

In the second study, Dr. William Cusick of Stanford Hospital in Connecticut studied the effect of the law during its first 10 months of implementation. Seven women were identified as HIV positive and two additional cases – a husband and a child – were identified after a positive test result. Without the testing requirements, Dr. Cusick acknowledges "we would have missed six of these nine cases." "The results of our study demonstrate that the law is working exactly as intended," he said. "So far all of the children are fine and we've followed them out for 12 months now," Dr. Cusick noted.[32]

Additional Benefits to Newborn HIV Screening

HIV diagnostics today offer noninvasive rapid testing that can help prevent perinatal transmissions. In addition to preventing babies from becoming infected with HIV during delivery, newborn screening offers many other benefits.

In most cases, children born to HIV infected women will not become infected during gestation or delivery, although they will carry detectable antibodies to the virus for some time. Those babies with infected mothers who are fortunate enough to escape HIV before and during delivery are still at risk for HIV if the mother breastfeeds. Studies have reported breast feeding transmission rates of 10 to 20 percent.[33] It is extremely tragic for a baby to escape infection only to become unknowingly infected by a loving, yet unsuspecting, mother via breastfeeding. Yet it continues to occur.

Newborn testing also offers additional hope to those babies who are infected. With knowledge of a child's HIV status, appropriate medical care can protect and enhance the child's health, and thereby prolong and improve life.

Pneumocystis carinii pneunomia (PCP) is the most common opportunistic AIDS related infection. The average survival time of a child who contracts PCP is one month. A study in *The New England Journal of Medicine* showed that two-thirds of children who developed PCP did not receive the disease-preventing prophylaxis because the physicians and families did not know the children were HIV-positive. "If infection is to be prevented, infants exposed to HIV must be identified earlier and prophylaxis must be offered to more children," the researchers stated.[34]

Research reported in the *American Journal of Public Health* showed that Vitamin A supplements alone will help infants with HIV fight off dangerous diarrhea, rashes, respiratory infections and other illnesses that could lead to death. This is a very inexpensive treatment with significant results.[35]

Furthermore, triple combination AIDS therapy, highly active antiretroviral therapy (HAART), can significantly improve the survival of children infected with HIV. The drug "cocktails" have proven to reduce death rates and improve the quality of life of children with HIV. "The effectiveness in infants and children is at least similar, or even greater, than observed in adults," according to researcher Patrizio Pezzotti of the University of Florence in Italy. The risk of death was 23 percent lower in children on monotherapy (one drug), 30 percent lower with double combination drugs and 71 percent down with standard triple drug therapy when compared to children who receive no antiretroviral drugs.[36]

Studies have also concluded that newborn HIV testing saves money. "Annual routine newborn HIV testing would encompass 3.8 million infants, identify 1,061 infected mothers, avoid 266 newborn infections, and would cost $7,000 per life-year gained" in the United States according to a study published in the *Journal of Acquired Immune Deficiency Syndromes*.[37] The average total lifetime charges for care of children with HIV infection is estimated at $491,936.[38] The researchers concluded that routine testing of newborns is, therefore, "cost effective."[39]

A study in Chicago found that the universal HIV testing would result in fewer infected newborns and save the city nearly $270,000 annually.[40]

Newborn HIV Testing is Widely Supported

Newborn testing is supported by the medical community, by the elected branches of the federal government and, overwhelming, by the public.

The American Medical Association, the nation's largest and most respected doctors organization, endorsed mandatory HIV testing of all pregnant women and newborns in 1996. "We have learned enough about the disease to know that the differences in those who are treated versus those who are untreated cuts by two-thirds the risk to the unborn child," said Robert E. McAfee, an AMA trustee and former president.[41] Surgeon

"We have learned enough about the disease to know that the differences in those who are treated versus those who are untreated cuts by two-thirds the risk to the unborn child"

General C. Everett Koop, M.D., stated that "as a former public health officer, I certainly approve of testing of newborns and believe that the information should be available to their parents and caregivers. I think this is the only sensible way to deal with the problem of HIV itself, but also would have the beneficial effect in the further transmission of the disease of AIDS."[42]

In 2000, the Congress passed without dissent, and President Clinton signed into law, the Ryan White CARE Act Amendments which contained a provision encouraging all states to enact newborn testing policies. States which pass such laws would be eligible for up to $4 million in federal funds to support state efforts to reduce perinatal HIV transmission. "This amounts to a federal endorsement of universal HIV newborn testing as

a routine practice," according to Congressman Tom A. Coburn, M.D., the bill's author and a practicing physician who has delivered AIDS babies.[43]

A 1995 poll of New York voters found four out of five respondents saying that mothers should be told the HIV status of their newborns. "The poll shows that the public's attitude is to err on the side of saving as many babies as possible," explained the Times Union newspaper. Support "runs across virtually every subgroup of those polled."[44] Nearly nine in 10 participants in a 1996 *USA Weekend* poll said they favored mandatory HIV testing of all pregnant women.[45] A scientific survey published in the January 2001 issue of *Obstetrics and Gynecology* found that 84.3 percent of women believe all pregnant women should be tested for HIV and three out of five felt such testing should be legally mandated.[46]

Editorial boards across the nation have echoed these same sentiments. *The Washington Post* has editorialized that "while counseling and voluntary testing are fine, all infants whose HIV status is unknown should be tested at birth and the results made known to parents, guardians and primary medical care givers."[47] *The Chicago Tribune* writes that newborn testing "would allow for quick treatment of infected babies. Some political groups have tried to make the testing of women and infants for the AIDS virus a privacy issue, but they are wrong. It is first and foremost a public health issue – one that affects the lives and well-being of the most vulnerable among us."[48] *The New York Times* "has long endorsed mandatory tests for the newborns" because it is "the best solution" to "insuring that all infected babies are identified for monitoring and treatment."[49] "To save the babies we need to know their HIV status at birth, and that of their mothers during pregnancy," writes the *Wall Street Journal*, then asking, "how did the American system arrive at a point where it discovers it can save HIV-infected babies and then decides not to?"[50]

The Arguments Against Newborn Testing

One must wonder why, with the obvious significant benefits and widespread support for newborn testing, such a program has not been recommended by the CDC or implemented nationally.

Over the past decade, newborn testing legislation has been introduced nationally and in numerous states. But, in nearly every case, AIDS activists have successfully derailed or fundamentally altered the underlying proposal with a set of unfounded and unproven claims. These arguments are:

- *Mandatory newborn HIV testing will deter women from seeking prenatal care and thereby, drive the epidemic underground.* "I feel sure we are going to see some women completely freaking out, committing suicide and running away from the whole situation," predicted Terry McGovern of the HIV Law Project.[51] The opposite has been the end result. New York's "Baby AIDS" law has orresponded with an increasing number of pregnant women both receiving prenatal care and HIV testing. A CDC funded study "found higher voluntary prenatal testing rates... after implementation of mandatory newborn HIV testing."[52] "Rates of

participation in prenatal care in New York State... have been increasing gradually over recent years," according to Dr. Birkhead who notes there has been "no [negative] detectable change" in prenatal participation trends "that might be related to the newborn testing program."[53]

- *Testing all newborns would be extremely expensive and would divert scarce resources away from other more effective interventions.* As previously noted, studies have found conclusively that universal newborn testing is the most cost effective intervention. Likewise in Connecticut, HIV testing rates for pregnant women jumped from 38.9 percent before the law to over 90 percent after the law was enacted.[54]
- *There are few health benefits to newborn testing, in effect, it is too little too late.* This could not be further from the truth. With prompt diagnosis and treatment, within 48 hours of birth, HIV infection can be prevented. Other at risk babies can be prevented from unknowingly being infected via breastfeeding. And for those children who are infected, appropriate treatment and proper medical monitoring can prolong and improve health outcomes.
- *Voluntary testing of pregnant women is the best approach to reducing perinatal HIV transmission.* At least 15 percent of HIV-infected pregnant women are not tested. Many do not receive appropriate prenatal care, some receive no prenatal care and others may simply refuse to be tested. It is not an "either/or" proposition, rather both approaches should be utilized. Prenatal screening provides for early intervention and newborn testing ensures that all babies are identified.

Clearly, far too many women and infants are being denied optimal medical care.

- *Testing is unreliable and may result in the treatment of uninfected children with highly toxic medications.* Rapid HIV tests can produce results in an average of 10 to 30 minutes. The sensitivity and specificity of these rapid assays are comparable to other HIV diagnostics. A negative rapid test does not require further testing, and negative results indicate the absence of HIV infection. There is a slim possibility that some tests may produce a "false positive" for HIV. Therefore, a reactive rapid test must be confirmed by a supplemental test. Results from a confirming test to the rapid return may be available within 12 hours of the infants' birth.[55] Studies have yet to show that ZVD has caused any significant adverse health consequence to children. Regardless, a short course of ZVD over several hours is far less dangerous than risking the alternative.
- *Testing a newborn for HIV also reveals the HIV status of the mother, and therefore, violates the mother's privacy, or her "right not to know her HIV*

status." Unfortunately, this is the crux, and underlying agenda of many AIDS activists. The dogma that places privacy over all else, including saving lives of women and babies is based on fear and outdated ideology rather than reality or sound public health. No scientific data indicates that loss of privacy has ever been an outcome of newborn testing policies. Anecdotally, few, if any, mothers have voiced the opinion that protecting the health of their baby jeopardizes their own personal rights. "You can't compare a baby's right to medication against a woman's right to confidentiality," explains Shelly Harrington – an HIV-positive mother of an HIV-positive teenager – who supports HIV testing for both pregnant women and newborns.[56] Hiding behind privacy will not save lives and it will not cure AIDS.

The New York Baby AIDS law, therefore, offers a paradigm that the CDC, other states, and other countries must embrace if perinatal HIV transmission is ever to be eliminated.

These arguments have either been discredited or remain unsubstantiated and run contrary to the existing medical, political, and popular sentiment regarding newborn HIV testing. "With New York clearly demonstrating that mandatory testing of newborns saves lives without endangering women, the argument should have been settled. But opponents are so steeped in ideology that facts don't matter," explains Wesley J. Smith, a well-regarded author on medical ethics.[57]

Conclusion

Unquestionably, the optimal method to prevent perinatal HIV transmission is to identify every infected pregnant woman as early as possible in her pregnancy and provide her with proper prenatal care and prophylaxis. Most women, when offered, will accept an HIV test.[58] Unfortunately, a significant proportion of HIV-infected mothers do not receive appropriate, or any, prenatal care and thereby go undiagnosed and untreated. Routine newborn screening provides a safety net to ensure that no HIV-exposed child is left to slip through the cracks and become needlessly infected. Such a policy also ensures that infected mothers who were previously unaware of their serostatus are given an opportunity to access medical care.

The New York program "has proven to be very effective in increasing prenatal testing rates while providing a safety net to facilitate early treatment for HIV positive newborns and their mothers who were unaware of their serostatus prior to delivery," according to Dr. Antonia C. Novello, New York's Commissioner of Health and former U.S. Surgeon General.[59]

This approach unquestionably has proven to be the single most successful baby AIDS prevention policy. It is more cost effective than other approaches and is the only one to identify all

those who are infected or at risk. The New York Baby AIDS law, therefore, offers a paradigm that the CDC, other states, and other countries must embrace if perinatal HIV transmission is ever to be eliminated.

"The success rate is phenomenal," New York Assemblywoman Nettie Mayersohn, the author of the state's Baby AIDS law proudly proclaims. She believes that "eventually it's going to happen" nationally. "It's just a question of how long it's going to take and how many [babies'] lives we are going to lose before we reach that point."[60]

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Author Affiliation

Roland Foster is a staff member of the U.S. House Subcommittee on Criminal Justice, Drug Policy and Human Resources where he is responsible for the oversight of the federal health agencies. Mr. Foster previously served as Legislative Director for Rep. Tom Coburn, MD, the author of the Ryan White CARE Act Amendments of 2000 and the federal Baby AIDS bill.

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Corning Tower, Empire State Plaza
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ANTONIA C. NOVELLO, M.D., M.P.H., DR. P.H.
Commissioner

Phone: (518) 474-2011
Fax: (518) 474-5450

April 24, 2006

Hon. Tom A. Coburn, M.D.
United States Senator
172 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Coburn:

Thank you for your March 23, 2006 letter requesting information on New York's experience in preventing mother-to-child HIV transmission (MTCT). The information presented below and the enclosed charts demonstrate New York's dramatic success in reducing both the transmission rate and the number of infected children born each year.

Question: Could you provide a brief overview of the New York law?

New York's comprehensive newborn HIV testing program was established by a 1996 statute amending New York's Public Health Law. The program was implemented February 1, 1997. New York State Department of Health regulations were enacted to provide the details of the program as well as to continue earlier regulations requiring clinicians practicing in regulated prenatal care settings to provide HIV counseling with testing presented as a clinical recommendation. Since the Department does not have the authority to regulate physicians in private practice, we worked with New York's professional medical organizations, including the American College of Obstetricians and Gynecologists, to establish HIV counseling with testing recommended as a standard of prenatal care regardless of setting.

The comprehensive prenatal and newborn program continued to evolve as studies on MTCT showed the benefit of abbreviated antiretroviral regimens begun in obstetrical settings and as advances in testing technology made rapid/expedited testing in obstetrical settings feasible. In 1999, the Department amended the newborn testing regulations to require expedited testing in obstetrical settings in cases where a pregnant woman presents for delivery with unknown or undocumented HIV status. In 2003, the regulations were again amended to require a 12-hour turnaround time for expedited test results, instead of the initial 48 hours allowed with the 1999 regulations. (See the enclosed graphic for an overview of current New York regulations governing prenatal and newborn HIV testing.)

The regulations for expedited testing in delivery settings prompted birth facilities to educate attending physicians and prenatal clinics to increase their prenatal testing rates. As a result, the vast majority of HIV-positive women are known prior to admission for delivery, with a small number identified through expedited testing in the obstetrical setting. Newborn HIV screening has become the "safety net." For example, acute HIV infection during pregnancy following a documented negative prenatal HIV test has been identified in a few cases by the infant's positive newborn screen.

Birth facilities are required to report data on maternal prenatal and expedited HIV testing to the Newborn Screening Program. The Department uses this data to monitor program implementation. In addition, all birth facilities in New York receive facility-specific performance data on a routine basis for internal quality improvement activities.

Question: Would you deem the New York law a success?

New York's newborn testing law is part of a comprehensive program for reducing MTCT, which includes the following goals:

- Ensuring access to prenatal care for all pregnant women;
- Establishing HIV counseling and recommended testing as a standard of prenatal care;
- Ensuring that all HIV-positive pregnant women are offered antiretroviral therapy (ART) for their own health and to reduce the risk of MTCT;
- Ensuring that HIV test information is transferred from the prenatal care site to the anticipated birth facility;
- Requiring expedited testing in the delivery setting for all women/newborns for whom prenatal HIV test results are not available; and
- Conducting HIV testing as a quality check on all newborn blood specimens submitted to the Department's Newborn Screening Program.

To reach these goals, the Department conducts surveillance; closely monitors compliance with regulations; sponsors enhanced outreach to high risk pregnant women not in prenatal care; provides consultation and technical assistance to hospital obstetrical departments; conducts quality reviews; and supports clinicians through education, training and the dissemination of state-of-the-art clinical practice guidelines.

The comprehensive program has had dramatic success. New York has the largest number of births to HIV-positive women in the United States, experiencing a high of 1,898 HIV-positive birth events in 1990. At that time, the mother-to-child transmission rate was estimated to be 25 to 30 percent, representing

approximately 475 to 570 HIV-infected infants born in New York in 1990. In the first year (1997) of routine newborn screening, there were 941 positive birth events with 97 (10.9 percent) infected infants. In 2004, there were 624 positive birth events and 16 (2.8 percent) infected infants. (See Charts 1 and 2 for additional data.)

Question: Has there been any evidence that this law has discouraged women from seeking prenatal care?

There is no evidence that pregnant women have been discouraged from seeking prenatal care or were going out-of-state to deliver following implementation of the comprehensive program. (See Chart 3.) The rate of acceptance of HIV testing among women in prenatal care increased and rates of no prenatal care in both HIV-positive and HIV-negative women in New York decreased.

Question: What was the percentage of pregnant women who received HIV testing prior to enactment of the law compared to the percentage receiving testing now?

Statewide data on HIV testing of pregnant women prior to the implementation of the comprehensive program is not available. In1997, when New York's comprehensive newborn program began, 64 percent of all pregnant women were aware of their HIV status on admission for delivery. In 2004, 95 percent of all women presenting delivery knew their HIV status. (See Chart 4.)

Question: What percentage of pregnant women refuse HIV testing? What are their reasons for refusing testing?

In 2004, 5 percent of women presenting for delivery did not have documentation of a prenatal HIV test. We suspect this represents women without prenatal care rather than women declining prenatal testing. A key factor in a woman's acceptance of prenatal HIV testing is the recommendation by her prenatal clinician that it is in the woman's and her infant's best interests to know her HIV status.

Question: What percentage of newborns and new mothers are sent home after delivery with an unknown HIV status? How does this compare to the percentage prior to the enactment of the law?

This information is not available prior to February 1, 1997. In 2004, less than 0.4 percent of the almost 240,000 infants born in New York State lacked documentation submitted to the Department on either prenatal testing or expedited testing in the obstetrical setting.

Question: What percentage of women and children that test positive for HIV antibodies are then referred into appropriate care?

Regulations require that birth facilities ensure that exposed newborns have diagnostic testing (such as DNA PCR testing) and that birth facilities submit the result of the first diagnostic test to the Department. The Department uses this as an indicator that exposed newborns are in care. To facilitate diagnostic testing of HIV-exposed infants, the Department has had a free diagnostic testing service for HIV-exposed infants since 1995.

An indicator, such as diagnostic testing of newborns, is not readily available to ensure HIV-positive pregnant/delivering women are in care. To address this, the Department is implementing an initiative to link HIV-positive pregnant women/delivering women to intensive case management, particularly those who have difficulty remaining in prenatal care or who deliver without prenatal care. In addition, all HIV-positive births are considered sentinel events. The AIDS Institute's review agent conducts medical record reviews on the prenatal, obstetrical, newborn and pediatric records associated with these events. Chart 5 provides trend data on antiretroviral regimens obtained from chart review for HIV-positive birth events from 1997 through 2002. This data is being updated to include 2003 and 2004.

Thank you for your inquiry regarding New York's experience in reducing mother-to-child HIV transmission. If you would like additional information, please contact Dr. Guthrie Birkhead, Director of the AIDS Institute, at (518) 472-5382, or by email at gsb02@health.state.ny.us.

Sincerely,

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner of Health

Enclosures
cc: Dr. Birkhead

HIV Counseling and Testing of Pregnant Women and Newborns in New York State



Regulatory requirement: HIV counseling of all pregnant women with HIV testing strongly recommended

Regulatory requirement: expedited HIV testing in labor, delivery with results available within 12 hours

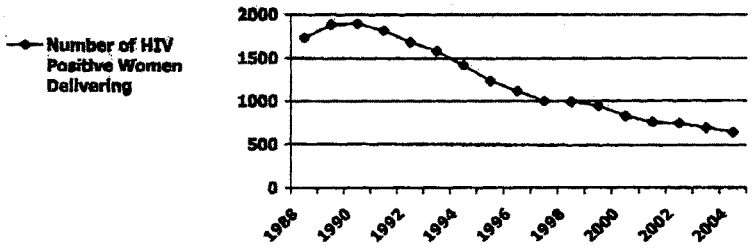
No HIV test history documented

Newborn HIV Screening Program

Mother: Consent required
Newborn: No consent required

Chart # 1

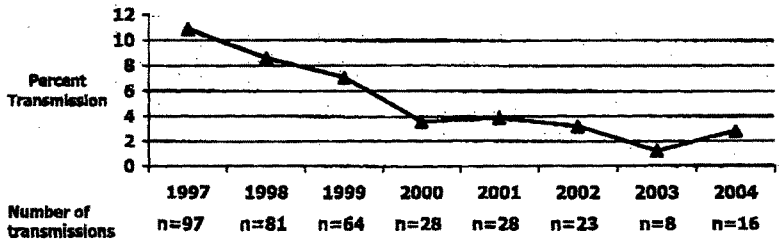
NYS Survey of Childbearing Women
HIV Prevalence By Year of Delivery: 1988-2004



Since 1990, there has been a 66% decline in the number of HIV-infected women giving birth in NYS: 1,898 in 1990 to 642 in 2004

Chart # 2

Mother-to-Child Transmission Rate
New York State, 1997-2004



Percent of deliveries by HIV positive mothers that resulted in HIV transmission to the baby

Chart # 3

New York State Birth Rate Per 1,000 Females Age 15-44
1993-2002

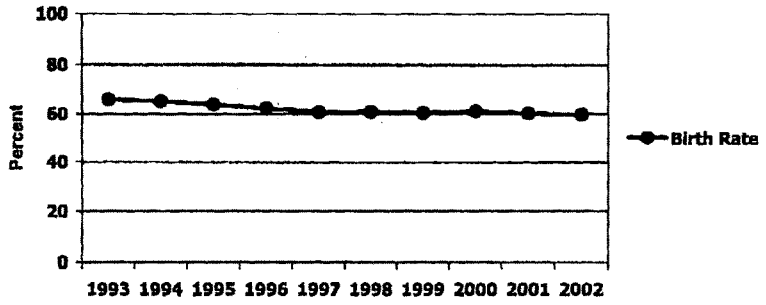
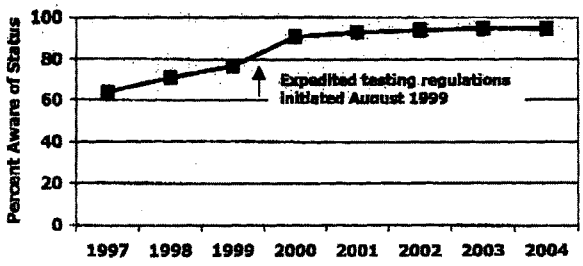


Chart # 4

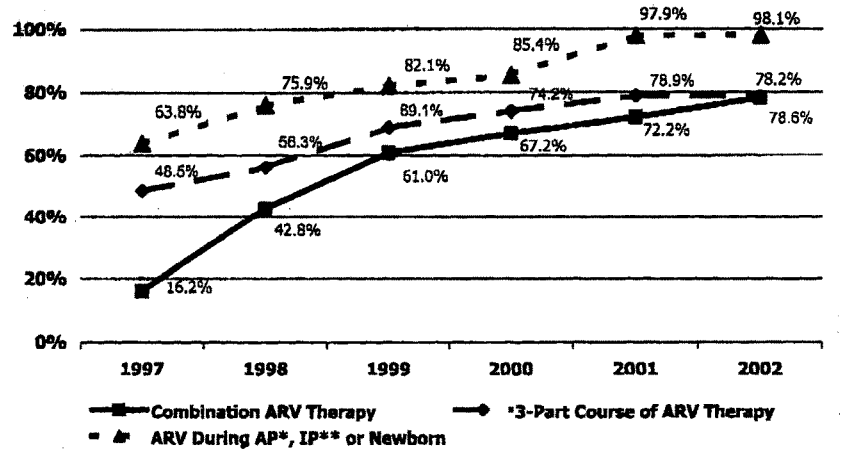
Women in NYS Aware
of HIV Status Before Delivery



From 1997 to 2004, the percentage of women aware of their HIV status before delivery increased from 64% to 95%.

Chart # 5

Trends in Health Care for HIV-Infected Women in NYS: Antiretroviral Therapy (ARV) and Elective C-Section, 1997-2002



*AP = Antepartum (prenatal) period **IP = Intrapartum (During labor and delivery)

The Associated Press
June 6, 2004, Sunday

Cases of HIV-infected newborns decline in New York

BYLINE: By ALICIA CHANG, Associated Press Writer
DATELINE: ALBANY, N.Y.

The number of newborns infected with HIV, the virus that causes AIDS, has reached a record low in New York, eight years after the state required that mothers be notified if their babies test positive.

Analyzing data from infants born between 1997 and 2002, the state Health Department reported a 78 percent drop in the number of infected babies born to HIV-positive mothers. The mother-to-infant infection rate was 2.4 percent in 2002 compared to 10.9 percent in 1997.

Perinatal HIV continues to be a problem worldwide. The World Health Organization estimates about 800,000 infants become infected with the virus each year, mainly in developing countries. In the United States, access to combination drug therapies and prenatal care has lowered the number of HIV-infected newborns, peaking in 1991 with 1,760 cases to as few as 280 in 2000, according to the federal Centers for Disease Control and Prevention.

Since 1987, New York has routinely tested newborns for a host of medical conditions including HIV, but mothers were not notified of the results. **The state credits the decline in HIV-positive newborns to a 1996 law requiring disclosure to mothers whose infants test positive so that newborns can seek immediate treatment.**

No consent is needed under New York state law for the HIV test on the infant. Prenatal HIV testing for mothers is not required, but about 95 percent of women get tested by the time they are ready to give birth, according to the state.

AIDS advocacy groups lauded the drop in mother-to-infant transmission rates, but said the state cannot take all the credit because many women were already choosing to get prenatal HIV testing before the 1996 law, and taking anti-AIDS drugs to inhibit the virus from spreading to the baby.

"This is a good example of a well-intentioned piece of legislation that was poorly targeted," said Christina Kazanas, director of policy and programs at the New York AIDS Coalition. "Testing the newborn after birth is not the primary way the transmission between mother-to-baby is being prevented."

Tracie Gardner of the Legal Action Center agreed, saying the law primarily serves to let women who refused to be tested during pregnancy know their HIV

status, but does not necessarily cut down on the infant infection rates.

"By the time the baby is born, you've missed critical opportunities to be able to actually prevent the baby from getting infected," she said.

Last year, the state mandated that birthing centers return results of blood tests on newborns within 12 hours instead of the original 48 hours because medical studies have shown that drug therapies worked best during that time frame.

Without treatment, about 1 in 4 HIV-infected women transmits the virus to her child. Of all the AIDS cases reported among children in the United States, 91 percent of them is through HIV transmission from mother to infant during pregnancy or by breast-feeding.

Although fewer AIDS babies were born in the United States in the last decade, federal officials worry that as the ranks of American women living with HIV grows, it may be difficult to eliminate mother-to-infant transmission.

On the Net:
NY Health Department AIDS Institute:
<http://www.health.state.ny.us/nysdoh/aids>

http://www.nypost.com/postopinion/opedcolumnists/43364.htm



N.Y.'S INFANT AIDS MIRACLE

By JOE DIAMOND

May 31, 2002 --

EVERY year, hundreds of American babies get the AIDS virus from their mother's milk. And these tragedies are entirely preventable: Congress just needs to follow New York state's lead.

From 1987 to '97, New York had the nation's highest number of pediatric AIDS cases. A major factor: misguided policy that tested all newborns for HIV for statistical tracking only, "blinding" the results from mothers and doctors. This, despite the availability by the early '90s of treatment for HIV-infected infants.

The rationale was that, because an infant's test result reveals the mother's HIV status, disclosing it would constitute forced AIDS testing of mothers and violate their "privacy rights." So infected babies were regularly sent home from the hospital to suffer and die untreated.

The presence of HIV antibodies does not always mean that a baby is HIV-positive, but it does indicate the mother is infected and can transmit HIV through breastfeeding. But thanks to privacy rules, infants born without HIV soon drink it in with their mother's milk.

In 1993, state Assemblywoman Nettie Mayersohn (D-Queens) had had enough. She drafted legislation to unblind the test results. Gay activists, civil libertarians, feminist groups and their allies in Albany lined up against the bill. But she was more determined, and in June 1996 Gov. Pataki signed the "Baby AIDS" law. Since then, New York's perinatal HIV transmission rate

has dropped from 25 percent to an all-time low of 3.5 percent. Over 99 percent of HIV-infected women and their children have received care.

Yet only New York and Connecticut now require universal unblinded HIV tests of newborns. The Women and Children's HIV Protection Act - introduced in Congress by Reps. Gary Ackerman (D-N.Y.) and Dave Weldon (R-Fla.) - would rectify this. "Hundreds of newborns will become infected with HIV each year and they will die, as will their mothers," they wrote to their fellow congressmen. "*Virtually every one of these children could be prevented from becoming infected with HIV.*" [emphasis added]

Under the bill, states seeking federal grants for treatment of HIV sufferers would have to do the following: 1) offer HIV counseling and testing to all women receiving prenatal care; 2) test for HIV any newborn whose mother has not taken a prenatal HIV test and promptly disclose the results to the parent or guardian so treatment can start immediately. This would essentially goad other states into adopting New York's approach.

Nationally, perinatally acquired AIDS began dropping in 1994 when the Public Health Service started recommending routine counseling and voluntary HIV testing of pregnant women and offering the AIDS medication zidovudine to infected mothers and infants.

But relying on voluntary testing of mothers without screening newborns as a backup is of limited value. The Centers for Disease Control and Prevention estimates that nearly 7,000 HIV-infected U.S. women give birth. Nearly half of pregnant women are still not tested.

The nation is so close to eradicating pediatric AIDS. But it needs that final kick-in-the-pants that the Ackerman-Weldon bill provides. As the two congressmen reminded their colleagues: "New York has eliminated the plague of Baby AIDS; why hasn't your state?"

Joe Diamond is the public affairs director at the Center for the Community Interest (communityinterest.org).

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

OFFICE OF COMMISSIONER

April 18, 2006

The Honorable Tom A. Coburn, M.D.
United States Senate
172 Russell
Washington, D.C. 20510

Re: HIV testing during pregnancy in Connecticut

Dear Senator Tom A. Coburn:

In response to your letter dated March 23, 2006, please find attached a copy of the statutes to which HIV testing for pregnant women and newborns was added in 1999. Prior to this legislation, prenatal care providers were required to counsel pregnant women about the benefits of HIV testing. The 1999 legislation builds on this requirement, adding two voluntary tests during the prenatal period with testing offered again at delivery for patients that decline. HIV testing is mandatory for the newborn if maternal HIV status is unknown at the time of delivery.

Your letter raises a number of specific questions that are addressed below.

Would you deem it a success? Appropriate HIV testing during pregnancy is an essential component in the prevention of perinatal HIV transmission. The 1999 legislation has had a dramatic impact on the rate of HIV testing in pregnant women in Connecticut. Prior to the legislation, 28% of prenatal records included documentation of HIV testing. At the same time testing rates for other infectious diseases including hepatitis B, syphilis and rubella were over 95%. With the enactment of this legislation, the HIV testing rate increased to 90% by two months after implementation. A study is currently being conducted to assess the prenatal testing rate for children born in 2003.

Has it enabled you to better identify and provide treatment to more women with HIV and children at risk for infection? The legislation ensures that all pregnant women and their providers have the best opportunity to learn about HIV infection in time to start treatment and also to take advantage of other prevention measures, such as appropriate use of Cesarean section and restriction on breastfeeding. During 1996-2004, 50-70 HIV-positive pregnant women delivered each year in a birth cohort of approximately 42,000 (1.2 - 1.7 per 1,000 births) (source: HIV surveillance). Approximately 60% of cases were known to be HIV positive prior to pregnancy both before and after legislation. Before legislation, however, 24% of HIV-positive women received their first diagnosis during pregnancy but this increased to 34% after the law was implemented with fewer women being identified at or after delivery (5% before the legislation to 1% after). For 5%-10% of cases, time of diagnosis could not be determined. However, the legislation has also been particularly important in cases where testing might not happen if it was based on risk assessment only. This includes cases where there is little or no

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perception of risk on the part of the patient/provider, and where the patient is not forthcoming about her risk or is unaware of her sex partner's risk. Although it happens infrequently, we have also learned that in some cases, an unexpected positive test has resulted in further testing in the family with identification of other HIV-infected persons, such as sex partners and other children.

Has there been any evidence that this law has discouraged women from seeking prenatal care? The results from a survey of obstetricians conducted in 2001 (asking about their experiences in 2000, the first full year after the law was implemented), suggested that they perceived little negative impact on their practices/patients (~90% response rate among prenatal care providers). For example, 84% indicated that the legislation had no impact or a positive impact on their practice/patients. An additional 6% indicated that the legislation had both positive and negative effects (6% indicated negative impact and 5% did not answer). Negative comments generally mentioned increased costs and time required for counseling. Conversely, however, many providers indicated that having the legislation facilitated testing. An analysis of birth record data for 2000 indicated that there was no significant overall decline in the number of prenatal visits or month of gestation at which prenatal care began.

What was the number of newborns with HIV/AIDS recorded annually prior to the law and in the most current year for which you have data? The number of HIV-positive newborns reported to the Department is the following: 1996=6 (of 67 exposed children); 1997=3 (69); 1998=1 (64); 1999=5 (70); 2000=1 (75); 2001=4 (68); 2002=0 (63); 2003=0 (50); 2004=0 (57). Final status cannot be determined for some children ranging from 1.4% to 22.0% of exposed children in a given year. While this can change with late reports, it is noteworthy that no HIV-infected newborns have been reported who delivered during 2002-2004. We would not attribute this progress entirely to the legislation but a high testing rate is prerequisite to a low transmission rate. Other factors play a role as previously mentioned, including progress that is being made in treatments that can reduce HIV viral load to a very low level thus reducing the risk inherent in blood exposure at delivery.

What percentage of pregnant women refused HIV testing? In the 2001 survey of obstetricians, 40% of respondents indicated that no patient had refused testing subsequent to the legislation, 44% indicated less than 3% of patients had refused testing, 8% indicated that 3-10% of patients refused, and 8% did not answer the question. In the year in which this survey was conducted, HIV testing was still controversial and there was likely some continuing adjustment in prenatal care provider practices and among pregnant women. In the years since enactment, the controversy surrounding the legislation has moderated significantly.

What are their reasons for refusing testing? Information about this was not collected as part of the survey of obstetricians. Anecdotally, we have been told that perception of low risk is a motivator in refusing testing. However, perception of risk seems to be HIV specific in that many fewer women have syphilis infection during pregnancy and that is not a test that is resisted.

What percentage of newborns and new mothers are sent home after delivery with an unknown HIV status? How does this compare to the percentage prior to the enactment of the law? Answering this question accurately would require an assessment of newborn records, which has not been done. The newborn testing provision of the legislation is meant to ensure that maternal HIV status is known for every pregnant woman. Although not part of the legislation, rapid

testing protocols have been implemented in all Connecticut hospitals with maternity services to ensure that HIV status is determined for pregnant women who have not had prenatal care or who may have previously declined testing.

What percentage of women and children that test positive for HIV antibodies are then referred into appropriate care? All HIV-positive women and their exposed newborns are referred to appropriate care. Patient compliance can occasionally be a problem for a number of reasons and in areas that are distant from tertiary care centers that specialize in HIV treatment, travel to the care center can create barriers to following through on referrals.

Finally, a comment about whether the legislative approach to increasing testing is preferred to education of providers and patients. The periodic assessments of testing rates for infectious diseases that have been conducted by the Department have shown that while the testing rate for hepatitis B increased from 52% to 95% in response to educational activities over a four-year period (1990-1993), the testing rate for HIV remained constant at 28% for four years (1996-1999) prior to the legislation.

If you have any other questions with respect to this matter, please do not hesitate to contact Aaron Roome, PhD, Supervising Epidemiologist, HIV/AIDS Surveillance Program. He may be reached at 860-509-7900.

Sincerely,

J. Robert Galvin, MD, MPH
Commissioner

19a-593 establishes that all pregnant women must receive HIV counseling during prenatal care and that if testing is refused on admission for delivery it must be in writing.

Sec. 19a-593. Testing of pregnant women and newborns.
(a) Each health care provider giving prenatal care to pregnant women in this state shall inform her, or ascertain from the woman's medical record that such information has already been provided to her, that HIV testing is a part of routine prenatal care and shall inform her of the health benefits to herself and her newborn of being tested for HIV infection. Such information shall be conveyed along with the counseling required by section 19a-582. The health care provider shall inform the patient that HIV-related information is confidential pursuant to section 19a-583. If the patient provides informed consent to an HIV-related test consistent with section 19a- 582, the health care provider responsible for HIV counseling under this section shall perform or arrange to have performed an HIV-related test and document the test result in the medical record.
(b) If, during the current pregnancy, an HIV-related test has not been documented in the patient's medical record at admission for delivery of the baby, then the health care provider responsible for the patient's care shall inform the pregnant woman as required under subsection (a) of this section and shall also inform her of the health benefits to herself and her newborn of being tested for HIV infection either before delivery or within twenty-four hours after delivery and, in the absence of specific written objection, shall cause such test to be administered.
(P.A. 95-269, S. 2; June Sp. Sess. P.A. 99-2, S. 29.)
History: June Sp. Sess. P.A. 99-2 deleted existing provisions requiring obstetrician-gynecologists to notify pregnant women of the availability of AIDS testing, added Subsec. (a) re information on HIV testing, performance of HIV testing and documentation of test results, and added Subsec. (b) re HIV information and testing at admission for delivery.
See Sec. 19a-55 re newborn infant health screening.
See Sec. 19a-90 re blood test of pregnant women.

19a-90 establishes that HIV testing must be offered twice during prenatal care, once early in pregnancy and once during the third trimester, consistent with syphilis testing.

Sec. 19a-90. (Formerly Sec. 19-47). Blood testing of pregnant women for syphilis and AIDS. (a) Each physician giving prenatal care to a pregnant woman in this state during gestation shall take or cause to be taken a blood sample of each such woman within thirty days from the date of the first examination and during the final trimester between the twenty-sixth and twenty-eighth week of gestation or shortly thereafter subject to the provisions of this section, and shall submit such sample to an approved laboratory for a standard serological test for syphilis and an HIV-related test, as defined in section 19a-581, provided consent is given for the HIV-related test consistent with section 19a-582. Each other person permitted by law to attend upon pregnant women in the state, but not permitted by law to take blood tests, shall cause a blood sample of each pregnant woman so attended to be taken by a licensed physician in accordance with the time schedule and requirements of this section and such sample shall be submitted to an approved laboratory for a standard serological test for syphilis and an HIV-related test, provided consent is given for the HIV-related test consistent with section 19a-582. A blood sample taken at the time of delivery shall not meet the requirement for a blood sample during the final trimester. The term "approved laboratory" means a laboratory approved for this purpose by the Department of Public Health. A standard serological test for syphilis is a test recognized as such by the Department of Public Health. The laboratory tests required by this section shall be made on request without charge by the Department of Public Health.

(b) The provisions of this section shall not apply to any woman who objects to a blood test as being in conflict with her religious tenets and practices.

(1949 Rev., S. 3836; P.A. 77-614, S. 323, 610; P.A. 79-39; P.A. 90-13, S. 3; P.A. 93-381, S. 9, 39; P.A. 95-257, S. 12, 21, 58; June Sp. Sess. P.A. 99-2, S. 31.)

History: P.A. 77-614 replaced department of health with department of health services, effective January 1, 1979; P.A. 79-39 simplified language and required blood sample taken during final trimester of pregnancy; Sec. 19-47 transferred to Sec. 19a-90 in 1983; P.A. 90-13 amended Subsec. (a) to specify that the test during the final trimester be done between the twenty-sixth and twenty-eighth week of gestation and added Subsec. (b); P.A. 93-381 replaced department of health services with department of public health and addiction services, effective July 1, 1993; P.A. 95-257 replaced Commissioner and Department of Public Health and Addiction Services with Commissioner and Department of Public Health, effective July 1, 1995; June Sp. Sess. P.A 99-2 added HIV-related test requirement in Subsec. (a).

See Sec. 19a-55 re newborn infant health screening.
See Sec. 19a-215 re required reporting of communicable diseases.
See Sec. 19a-593 re testing of pregnant women and newborns.

19a-55 establishes HIV testing for newborn infants unless the mother was tested during prenatal care

Sec. 19a-55. (Formerly Sec. 19a-21b). Newborn infant health screening. Tests required. Fees. Regulations. Exemptions. (a) The administrative officer or other person in charge of each institution caring for newborn infants shall cause to have administered to every such infant in its care an HIV-related test, as defined in section 19a-581, a test for phenylketonuria and other metabolic diseases, hypothyroidism, galactosemia, sickle cell disease, maple syrup urine disease, homocystinuria, biotinidase deficiency, congenital adrenal hyperplasia and such other tests for inborn errors of metabolism as shall be prescribed by the Department of Public Health. The tests shall be administered as soon after birth as is medically appropriate. If the mother has had an HIV-related test pursuant to section 19a-90 or 19a-593, the person responsible for testing under this section may omit an HIV-related test. The Commissioner of Public Health shall (1) administer the newborn screening program, (2) direct persons identified through the screening program to appropriate specialty centers for treatments, consistent with any applicable confidentiality requirements, and (3) set the fees to be charged to institutions to cover all expenses of the comprehensive screening program including testing, tracking and treatment. The fees to be charged pursuant to subdivision (3) of this section shall be set at a minimum of twenty-eight dollars. The commissioner shall adopt regulations, in accordance with chapter 54, specifying the abnormal conditions to be tested for and the manner of recording and reporting results. On or before January 1, 2004, such regulations shall include requirements for testing for amino acid disorders, organic acid disorders and fatty acid oxidation disorders, including, but not limited to, long-chain 3-hydroxyacyl CoA dehydrogenase (L-CHAD) and medium-chain acyl-CoA dehydrogenase (MCAD).

(b) The provisions of this section shall not apply to any infant whose parents object to the test or treatment as being in conflict with their religious tenets and practice.

(February, 1965, P.A. 108, S. 1, 2; P.A. 77-614, S. 323, 610; P.A. 78-193, S. 1, 2, 4; P.A. 92-227, S. 1, 2; P.A. 93-381, S. 9, 39; P.A. 95-257, S. 12, 21, 58; June 18 Sp. Sess. P.A. 97-8, S. 26; June Sp. Sess. P.A. 99-2, S. 30; P.A. 02-113, S. 1; June 30 Sp. Sess. P.A. 03-3, S. 5.)

History: P.A. 77-614 replaced department of health with department of health services, effective January 1, 1979; P.A. 78-193 included tests for hypothyroidism and galactosemia and transferred regulation power from department to commissioner; Sec. 19-21b transferred to Sec. 19a-55 in 1983; P.A. 92-227 amended Subsec. (a) to add sickle cell disease, maple syrup urine disease, homocystinuria and biotinidase deficiency to list of diseases for infant testing and to detail responsibilities of the commissioner in administering the program; P.A. 93-381 replaced department of health services with department of public health and addiction services, effective July 1, 1993; P.A. 95-257 replaced Commissioner and Department of Public Health and Addiction Services with Commissioner and Department of Public Health, effective July 1, 1995; June 18 Sp. Sess. P.A. 97-8 added congenital adrenal hyperplasia to the list of diseases tested for; June Sp. Sess. P.A. 99-2 amended Subsec. (a) by replacing "infants twenty-eight days or less of age" with "newborn infants", adding HIV-related test, adding provision that tests be administered as soon after birth as is medically appropriate and that test may be omitted if done under other statutes, and adding "consistent with any applicable confidentiality requirements" in Subdiv. (2); P.A. 02-113 amended Subsec. (a) to add requirement for testing of "other metabolic diseases", to add a minimum fee requirement of twenty-eight dollars, and to add requirement that on or before January 1, 2003, the regulations shall include testing for amino acid disorders, organic acid disorders and fatty acid oxidation disorders; June 30 Sp. Sess. P.A. 03-3 amended Subsec. (a) by changing date for regulations requiring testing for certain disorders from January 1, 2003, to January 1, 2004, effective August 20, 2003.

The Advocate (Connecticut)
March 14, 2003

Number of HIV-infected babies drop after new law decrease

By Asante Green
Staff Writer

STAMFORD -- A state law mandating that doctors notify pregnant women about HIV counseling and testing has significantly decreased the number of infected newborns, health officials say.

The rate of neonatal HIV infection dropped from 11.9 percent in 1995 to 1.9 percent after mandated screening in 1999, when the state required health-care providers to notify pregnant women that HIV testing is part of routine care.

According to the new law, if expectant mothers refuse testing, newborns are tested without their consent.

"There were some women out there who were infected with HIV who didn't have readily identifiable risk factors who, because of that, weren't screened," said James Hadler, a state epidemiologist. "With the screening law, every pregnant woman is screened."We also knew there were highly effective treatments that could keep a mother from passing HIV to her child," he said. "The only way you could apply that treatment was if you knew before birth that the mother was infected."

There is a 25 percent chance that an infected mother can transmit the virus to her unborn baby if she is untreated, and a 2 percent chance if the mother is treated, Hadler said.

Under a policy of voluntary screening from 1992 to 1998, one to three cases of HIV pregnancy were documented in Stamford, according to a study by Stamford Hospital published in the January edition of Connecticut Medicine.

With universal screening, many more cases have come to light.

Before the mandatory screening law was passed, roughly 30 percent of mothers were screened statewide, identifying 70 percent to 90 percent of those infected with HIV, Hadler said.

From 1995 to 1999, before the law, 60 to 65 babies were born with HIV each year in Connecticut, Hadler said. Statistically, fewer than one baby is born annually with HIV today, he said.

The purpose of the Stamford Hospital study was to report the impact of mandatory

prenatal HIV screening, said Dr. William Cusick, associate director of Maternal Fetal Medicine at Stamford Hospital.

"The reduction in neonatal HIV infection documented at our institution has mirrored the success experienced statewide," Cusick said.

A total of 2,352 infants were born to 2,239 mothers at Stamford Hospital during the study.

Seven pregnant women identified as HIV positive were treated with anti-HIV injections to reduce transmission to their unborn babies. All seven of the infants born to these mothers tested negative for HIV, according to the study.

"We estimated that seven of the nine cases of HIV infection we identified would have been missed under a policy of voluntary HIV screening," Cusick said.

The other two cases were the husband and 18-month-old baby of an HIV-infected woman -- cases that also would have been missed if the pregnant mother was not informed that HIV testing was part of routine obstetric care, Cusick said.

"Prenatal testing gives you your best opportunity to prevent transmission to the baby," he said. "Within the first 10 months the law was enacted, we found that women didn't have a problem with accepting the test so long as we told them it was part of routine lab tests, that everyone needed to get done," Cusick said.

Debra Katz, director of HIV Programs for the Stamford Health Department, said the department and the hospital have encouraged prenatal and neonatal screening for eight years.

"It is much more important to test the mother than the baby," Katz said. "If you find out earlier that the mother is infected, you could test and treat the mother to decrease the chances of the baby getting the disease."

Arkansas Department of Health and Human Services

Division of Health

Paul K. Halverson, DrPH, Director

P.O. Box 1437, Slot H-39 Little Rock, AR 72203-1437 • 501-661-2400 • TDD: 1-800-234-4399

April 14, 2006

The Honorable Tom Coburn, M.D.
United States Senator
800 North Baltimore Avenue, Suite 800
Tulsa, OK 74119

Dear Dr. Coburn,

The Arkansas law requiring testing of pregnant women in Arkansas was enacted in as Act 963 of 1997. The law states that:

> Every physician or other health care provider who attends pregnant women must test each woman for syphilis, HIV, and Hepatitis B and inform her of the risks of transmitting these infections to her child. The patient has the option to refuse to be tested; in this case, refusal should be noted in the patient's medical record.

One of the factors that greatly influenced the success of this Act and support for it in the Arkansas General Assembly was that Arkansas has required "named reporting" of HIV infected individuals since 1988 when the Act 96 of 1913 was amended to include HIV and AIDS. This enabled the public and private medical providers to track HIV infected clients and impacts the health outcome of the HIV infected client. If the client is pregnant we are able to impact both the mother's and the baby's health outcome. Success can be measured by the fact that Arkansas has not had a reported case of perinatal HIV transmission since 2002. From 1983-1997, 44 cases of perinatal HIV transmission were reported. Since 1997 (the year we enacted required prenatal testing) only 17 cases of perinatal transmission have been reported.

Currently, in Arkansas the HIV test is provided as part of a standard battery of screening tests performed for all pregnant women seeking prenatal care. Most HIV infected pregnant women identified in Public Health Clinics are referred to the University of Arkansas Medical Sciences Campus (UAMS) "High Risk Clinic". UAMS provides the specialized care and follow-up the HIV infected woman and her unborn child require. Upon birth, infants of HIV infected mothers are transferred to the Arkansas Children's Hospital. If eligible, the women are also referred to the Title II Ryan White Care Act funded Consortia. The Consortia enroll the eligible client in the AIDS Drug Assistance Program (ADAP) and provide supportive services. Reasons for pregnant women not being tested for HIV prior to delivery vary from those who already know their HIV status, to women who did not return for prenatal care, to women who received no prenatal care and delivered at home, to the very small percentage who choose not to be tested.

During 2005, 5,063 of the 5,483 (92%) women attending public maternity clinics in Arkansas were tested for HIV, and of those, 15 (.003%) tested positive for HIV. All 15 received prenatal care and all 15 delivered infants. We are still tracking the serological status of the infants (for up to 18 months) to determine if they are HIV infected. For both Arkansas' public and private providers in 2005, approximately 35,046 women delivered infants. From our reporting, HIV Surveillance and the Pregnancy Risk Assessment Monitoring Survey (PRAMS), 86% of the 35,046 women were tested for HIV. A total of 23 infants were born to HIV infected mothers during 2005 and none of the infants have sero-converted.

We have no evidence to support the concern that adding the HIV screening to routine prenatal care has caused women to be less likely to seek prenatal care.

Thank you for recognizing Arkansas as a leader in this area and we hope this information is useful. Please feel free to contact me at (501) 661-2000 if you have any additional questions.

Sincerely,

Paul K. Halverson, DrPH
Director of Health and State Health Officer

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
CORDELL HULL BLDG.
425 5TH AVENUE NORTH
NASHVILLE TENNESSEE 37247

PHIL BREDESEN
GOVERNOR

KENNETH S. ROBINSON, M.D.
COMMISSIONER

April 19, 2006

The Honorable Tom A. Coburn, M.D.
U.S. Senator
United States Senate
Washington, DC 20510-3604

Dear Senator Coburn:

I am responding to your letter requesting information about Tennessee's experience with HIV testing for pregnant women and perinatal HIV transmission. Tennessee's law on HIV testing for pregnant women was passed in 1997 and is considered "opt out" legislation; requiring a pregnant woman to be administered a test for HIV unless she "opts out." This has resulted in early identification and treatment of pregnant women and their infants, resulting in a significant decrease in perinatal transmission of HIV. Tennessee considers this statue to be a success.

The chart attached illustrates a comparison of births by HIV infected women to the numbers of infants infected through perinatal transmission in Tennessee since the law was enacted. We do not have the number of births that occurred by HIV infected women in 1996, the year prior to the legislation. However, we do know that there were 15 HIV infected infants born during that year. Although there have been fluctuations in the annual numbers of infected infants, the table demonstrates a decreasing trend of perinatal transmission.

In an effort to further lower the number of HIV infected infants, a partnership was created between the Department of Health and a large urban hospital where most of the infected infants have been delivered. Beginning in early summer of 2006, the hospital will be offering the HIV rapid test in labor and delivery to any woman whose HIV status is unknown. Since the law is "opt out," unless the woman specifically refuses, she will be tested. We believe that this increase in testing will further lower the number of HIV infant transmissions.

There is no evidence in Tennessee that the law has discouraged women from seeking prenatal care. An analysis of the percentage of women with no prenatal care before

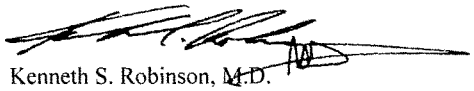
delivery indicates no significant change from 1996 to 2004. The percentage of pregnant women who received no prenatal care fluctuated from 1.3 to 1.5 during that time with no discernable trend.

We do not have data on the percentage of women who refused testing or their reasons. There is no requirement in the legislation for providers to report this information; anecdotally, we believe the number to be very small. We also do not have data on the percentage of newborns and new mothers that are sent home after delivery with an unknown HIV status. Our belief is that most of the transmission is occurring in substance abusing women who do not seek prenatal care or in infected women who have not developed antibodies at the time of the initial test.

All of the women and children who test positive in Tennessee are referred into care through our network of AIDS Centers of Excellence. Both Memphis and Nashville, where most of the births to HIV infected women occur, have strong outreach and case management programs for finding and following HIV infected pregnant women and their infants. The program at the Comprehensive Care Center in Nashville has provided care for over 139 HIV infected pregnant women delivering 150 infants without a single infant transmission. This has been accomplished through intensive case management during the prenatal period and the infant's first months. Although very labor intensive and time consuming, the program has demonstrated cost effectiveness.

The experience in Tennessee with prenatal HIV testing has been a very positive one with demonstrated decreased transmission. We are certainly supportive of the efforts to make HIV testing a routine part of prenatal care. If you have additional questions, please do not hesitate to contact me.

Sincerely,

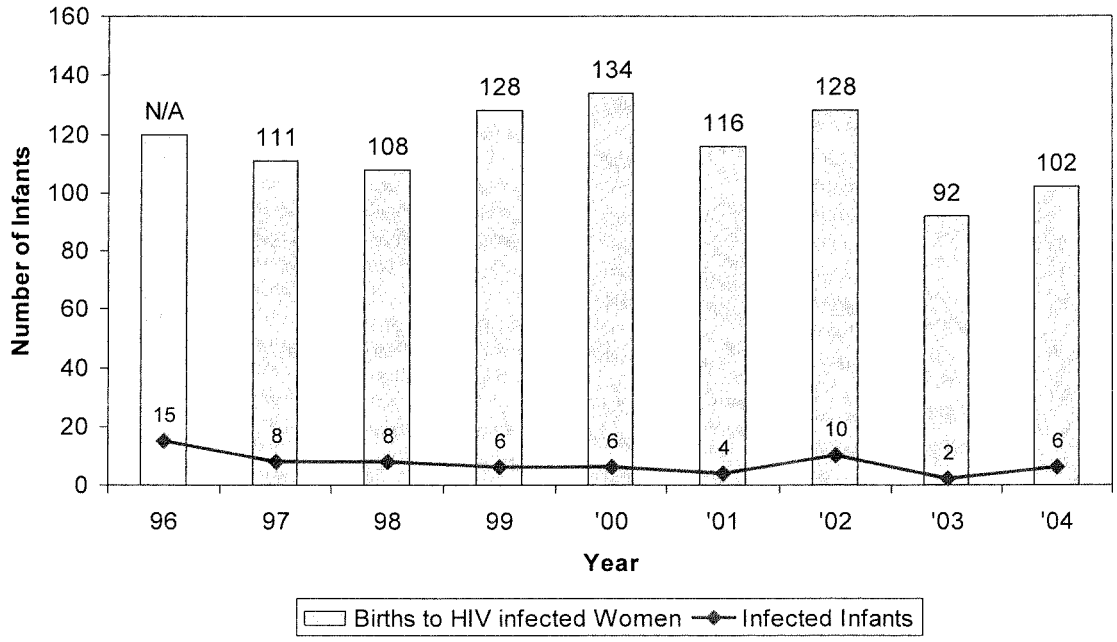


Kenneth S. Robinson, M.D.
Commissioner

KSR/AJS

Attachment

A Comparison of Total Births by HIV Infected Women to Total Infants Infected Through Perinatal Transmission in Tennessee 1996-2004



http://www.denverhealth.org/News/NewsRelease.aspx



DENVER HEALTH NEWS

Level One Care for ALL

777 Bannock Street, MC 0278, Denver, CO 80204 Phone: 303-436-6606 Fax: 303-436-5131

Pregnant women readily accept HIV testing, Denver Health study shows

Monday, July 28, 2003
Contact: Tony Encinias
303-436-5401
Bill Burman, M.D.
303-436-8197

A four-year study of more than 12,000 pregnant women at Denver Health Medical Center indicated that more than 98 percent voluntarily agreed to an HIV test, while less than 1% (20 patients, 0.2%) refused. An additional 197 women were not tested, but were not documented as having refused testing. **Most of the 197 women did not have prenatal care, making it difficult to perform screening tests prior to delivery.**

A multidisciplinary team of Denver Health infectious disease, OB/GYN, and family practice physicians and a graduate student reviewed records of women who delivered at Denver Health between January 1, 1998 and December 31, 2001.

"Perinatal transmission of HIV is preventable," explained Bill Burman, M.D., the study's principal investigator, and medical director of Denver Public Health's Infectious Diseases Clinic, "but this approach to HIV prevention will only work if a high percentage of pregnant women agree to be screened."

Testing programs requiring lengthy counseling and written consent, called opt-in, have substantially lower rates of HIV screening than do testing programs using verbal consent and recommending HIV screening to all pregnant women, called opt-out.

The 98.4 percent rate of screening at Denver Health is the highest rate of HIV screening in pregnancy that has been reported in the United States. Burman said the study confirms that the opt-out strategy is highly effective in a large urban health care system. The group hopes to increase the rate of screening to nearly 100% now that a convenient rapid HIV test is available.

Previous studies in the U.S. demonstrated HIV screenings were lower (from 31 - 85 percent), leading to concerns that a significant number of women would refuse such screenings during their pregnancy.

Denver Health, formerly known as Denver General Hospital, integrates acute hospital and emergency care with public and community health and includes the Rocky Mountain Regional Trauma Center, Denver's 911 emergency medical response system, Denver Health Paramedic Division, 10 family health centers, 13 school-based health clinics, the Rocky Mountain Poison and Drug Center, NurseLine, Correctional Care, Denver CARES, Denver Public Health, Denver Health Medical Plan, Rocky Mountain Center for Medical Response to Terrorism, Mass Casualties and Epidemics and the Denver Health Foundation.

The Associated Press
May 12, 1995, Friday, PM cycle

In Surprise Move, CDC Ends AIDS Tests on Newborns

By LAURAN NEERGAARD, Associated Press Writer

DATELINE: WASHINGTON

American babies will no longer be tested for the AIDS virus at birth as part of the federal government's efforts to track the growing epidemic.

The Centers for Disease Control and Prevention, in a surprise move, announced the suspension of the $ 10 million newborn HIV survey Thursday, telling Congress it was time to re-evaluate whether those funds could be better spent.

The move came less than an hour after a congressman pleaded for the CDC to tell all mothers the results of those AIDS tests, which have been conducted anonymously in 45 states since 1988.

The testing has been kept anonymous because 80 percent of babies born to HIV-infected mothers never develop AIDS - but they test positive at birth since all newborns carry their mother's immune cells. Thus, testing newborns was the CDC's way to track AIDS in young women.

"How unconscionable is it to let a mother think she's taking home an otherwise healthy infant when there are things that can be done to help that child?" Rep. Gary Ackerman, D-N.Y., asked a House Commerce health subcommittee debating the issue.

He introduced legislation to "unblind" the CDC survey, requiring any state that participates to give the mother the test results so she could quickly seek treatment if her child proves to be infected.

The CDC's decision could kill Ackerman's bill; he didn't immediately comment.

AIDS activists call Ackerman's bill tantamount to mandatory AIDS testing of women, which they say will scare some women away from health care. But they were stunned by the CDC's suspension of the survey as well.

"This is one more misstep in a series of missteps," said Terry McGovern of the HIV Law Project in New York. "It was a political decision. ... The study has been really useful - in the early years, it was only evidence we had that" AIDS was fast becoming a danger to heterosexual women.

The CDC deemed the newborn testing unnecessary because it is about to call for every pregnant woman - 4 million annually - to be voluntarily tested for AIDS early in her pregnancy, CDC's Dr. Helene Gayle told the congressional hearing.

The CDC guidelines, which become the nation's standard of care, come because new research shows women can cut by two-thirds their chance of infecting their babies if they take the drug AZT during early pregnancy.

"We can save hundreds of babies' lives this way," CDC AIDS chief Dr. James Curran said. "And every pediatrician will know every baby who's exposed."

Lawmakers questioned whether the CDC was right to disband the survey - and to oppose Ackerman's attempt to expand it into a tool to diagnose babies.

Doctors automatically test newborns for syphilis and tell the mothers the results, noted Rep. Tom Coburn, R-Okla., himself a doctor who insists his pregnant patients be tested for AIDS.

"Is that an adequate policy to control this epidemic?" he asked.

"The whole nature of HIV is very different from the nature of syphilis," a more treatable disease, Gayle responded. She added that CDC's decision isn't final - she'll ask states and outside experts whether the survey should be reestablished.

AIDS is the fourth-leading cause of death among women of childbearing age, and is increasing by about 8 percent a year among women. Some 7,000 HIV-infected women give birth each year and 2,000 of their babies are infected.

Chicago Tribune
July 29, 2003

Ignorance hinders the AIDS fight, researchers say
More HIV testing, awareness urged

By Peter Gorner
Tribune science reporter

New studies released Monday underline the major role ignorance still plays in controlling the 20-year-old HIV and AIDS epidemic in this country.

"Although we've seen great progress in preventing the disease, an estimated 850,000 to 950,000 Americans are now living with HIV, a quarter of whom are unaware of their infection," said Dr. Ronald O. Valdiserri, co-chairman of a summit conference on HIV and AIDS prevention in Atlanta, during a news conference Monday.

Three thousand public health experts, researchers and advocates for the prevention and treatment of AIDS are attending the three-day 2003 National HIV Prevention Conference, sponsored by the Centers for Disease Control and Prevention in Atlanta, which ends Tuesday.

Taken as a whole, the research presented Monday suggested ways to bolster several fronts in fighting AIDS, including making HIV tests a routine part of medical care, expanding access to the test, increasing attention to prevention among people who carry the virus and reducing mother-to-child transmissions.

Last year 16,371 Americans died of AIDS, and about 40,000 new cases are reported annually, Valdiserri said.

He restated preliminary 2002 CDC data that showed a 2.2 percent increase in new AIDS diagnoses and a 5.9 percent decrease in deaths.

Valdiserri and other federal health officials also sounded an alarm that the effectiveness of a life-prolonging drug regimen, commonly

known as drug "cocktails," introduced in the mid-1990s may have hit a plateau. This was attributed to failure of the treatment in some cases, the difficulty that many patients have following a complex drug regimen and late diagnosis and treatment.

"Efforts to increase the number of HIV-infected people who are aware of their HIV status and to link them to testing, treatment and prevention services are critical to reducing new infections," Valdiserri said.

"I don't think we're losing the war. But we're certainly not finished with the war."

Researchers emphasized the psychological difficulties faced by many health care providers and patients in explicitly discussing risky sexual behavior and the dangers they pose for infection.

For instance, one study of primary care clinics across the nation found that doctors and nurses rarely offered HIV-infected patients information about how to protect their partners.

Another study detailed a program to bring prevention counseling to a gay bathhouse. But the effort suffered from low rates of return for test results--only 40 percent of those with HIV infections followed up to learn their status, even when told they could get the results by telephone.

Transmission of HIV by mothers to their newborns remains a problem despite major advances, the CDC said.

In two surveys of recently pregnant women, 20 percent reported they had never been tested for HIV, despite government recommendations since 1995 that all pregnant women be voluntarily tested.

"Each case of mother-to-child HIV transmission represents a failure of our public health system," said Dr. Julie L. Gerberding, CDC director.

"Every pregnant woman should be screened for HIV so that treatment

can be offered, if needed, to protect mother and child."

About 300 babies a year contract the virus from their mothers, despite a sharp drop during the last decade due to effective anti-viral drugs to prevent such transmission.

But as many as 40 percent of women of childbearing age are unaware such treatments exist, according to another CDC study. And among those who are pregnant, foreign-born women may be nearly twice as likely to refuse HIV testing.

Women were much more likely to be tested during pregnancy if they were younger than 25, African-American, had a high school education or less, or if they received prenatal care through a public provider or Medicaid, the study found.

Data about foreign-born women came from a survey of 486 foreign-born and 330 U.S.-born women conducted by Dr. Getahun Aynalem and colleagues at the Los Angeles County Department of Health.

Being in a monogamous relationship was the primary reason cited by the foreign-born women who declined testing.

However, 5 percent of American-born women who decided against testing cited having taken previous tests that had come back negative.

Researchers also took note of several studies positively evaluating the OraQuick HIV test that can provide accurate results in about an hour for women whose HIV status is unknown at the time of labor.

The test is not yet available in Illinois, but a bill authorizing it passed the legislature and is awaiting the governor's signature, said Tammy Leonard, spokesman for the Illinois Department of Public Health.

MMWR™
Morbidity and Mortality Weekly Report

Weekly November 15, 2002 / Vol. 51 / No. 45

HIV Testing Among Pregnant Women — United States and Canada, 1998–2001

Since 1994, the availability of increasingly effective antiretroviral drugs for both the prevention of perinatal human immunodeficiency virus (HIV) transmission and maternal treatment has resulted in a greater emphasis on prenatal HIV testing and substantial increases in prenatal testing rates. In 2000, preliminary data indicated that 766 (93%) of 824 HIV-infected women in 25 states knew their HIV status before delivery (CDC, unpublished data, 2002). However, an estimated 280–370 perinatal HIV transmissions continue to occur in the United States each year (*1*). The primary strategy to prevent perinatal HIV transmission is to maximize prenatal HIV testing of pregnant women. States and Canadian provinces have implemented three different prenatal HIV-testing approaches. To assess their effectiveness, CDC reviewed prenatal HIV-antibody testing rates associated with these approaches. Medical record data suggest that the "opt-in" voluntary testing approach is associated with lower testing rates than either the "opt-out" voluntary testing approach or the mandatory newborn HIV testing approach.

Under the opt-in approach, women typically are provided pre-HIV test counseling and must consent specifically to an HIV-antibody test. Under the opt-out approach, women are notified that an HIV test will be included in a standard battery of prenatal tests and procedures and that they may refuse testing (*2*). Under mandatory newborn HIV testing, newborns are tested for HIV, with or without the mother's consent, if the mother's HIV status is unknown at delivery.

Three methods were used to estimate prenatal testing rates among all women who delivered, regardless of whether they received prenatal care. First, eight U.S. areas that participated during 1998–1999 in CDC's Active Bacterial Core Surveillance/Emerging Infections Program (ABC) Network assessed HIV testing during prenatal care and ≤2 days before delivery by reviewing a stratified random sample of labor and delivery records and prenatal records forwarded to birthing hospitals (*3*); in collaboration with CDC, network staff received a sample of records from all birthing hospitals in the surveillance areas and weighted testing rates to represent all live-born infants in those areas. Second, public health investigators in each of the five Canadian provinces tallied the number of HIV tests among pregnant women that were submitted to provincial laboratories and divided the total by an estimate of all live and stillborn births in each province during the same year. Third, CDC analyzed weighted data collected in 1999 by interviewers in nine states for CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) (an ongoing, population-based survey conducted in 32 states and New York City among women who have given birth during the preceding 2–6 months [*4*]), who had asked women if they had been tested for HIV during pregnancy. Data on state prenatal HIV-testing policies were obtained from the American College of Obstetricians and Gynecologists (*5*).

HIV-testing rates varied depending on which approach to testing was used. Rates for states using the opt-in approach to prenatal HIV testing included in the ABC Network ranged from 25% to 69% (Table 1), testing rates in Canada ranged from 54% to 83% (Table 2), and rates derived from PRAMS data ranged from 61% to 81% (Table 3). Two U.S. states (Arkansas and Tennessee) and two Canadian provinces (Alberta, and Newfoundland and Labrador) reported using

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an opt-out prenatal HIV-testing policy. ABC Network data indicated that Tennessee had a testing rate of 85% (Table 1). Canada's population-based data indicated a 98% testing rate in Alberta and a 94% testing rate in Newfoundland and Labrador (Table 2). PRAMS interview data indicated a 71% testing rate in Arkansas (Table 3), compared with a 57% testing rate early in 1997 before the law was implemented (Arkansas Department of Health, personal communication, 2002). Two states (New York and Connecticut) require HIV testing of newborns whose mothers were not tested during pregnancy. In New York, an ABC Network review of medical records in seven counties in the Rochester area indicated that the proportion of pregnant women who received a prenatal HIV test increased from 52% of 438 charts during January 1998–July 1999 to 83% of 112 charts during August–December 1999 after New York required that newborn HIV testing results be made available within 48 hours of specimen collection (Table 1). PRAMS data for 1999 indicated that the proportion of women statewide who reported having received an HIV test during pregnancy increased from 69% of 758 women during January–July to 93% of 502 during August–December (Table 3). In separate, statewide analyses of prenatal testing reported on newborn metabolic screening forms from all live-born infants, New York reported prenatal HIV-testing rates of 89% in 2000 and 93% in 2001 (New York State Department of Health, personal communication, 2002). In Connecticut, an ABC Network review of 668 charts indicated a testing rate of 31% during January 1998–September 1999, compared with 81% of 93 charts reviewed during October–December 1999 after enactment of the mandatory newborn testing law (Table 1).

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Editorial Note: Prenatal HIV testing affords the best opportunity for the prevention of perinatal HIV transmission. On the basis of clinical trial data, perinatal HIV-transmission rates among HIV-infected women who begin antiretroviral treatment during pregnancy are as low as ≤2% (*6*), compared with 12%–13% early transmission rates among women who do not begin preventive treatment until labor and delivery or after birth (*7*) and 25% among women who receive no preventive treatment (*8*).

TABLE 1. Number of medical charts reviewed and percentage of charts with a documented prenatal HIV test for pregnant women, by testing approach and area — Active Bacterial Core Surveillance/Emerging Infections Program Network, eight states, 1998–1999

State	Testing approach	No. charts reviewed	% with HIV test*	(95% CI†)
Tennessee (five counties)	Opt-out§	623	85%	(82.1%–88.5%)
New York (seven counties in the Rochester area)	Mandatory newborn testing¶ without expedited testing requirement**	438	52%	(47.3%–57.1%)
	Mandatory newborn testing; results returned within 48 hours††	112	83%	(75.0%–91.5%)
Connecticut	Opt-in§§	668	31%	(27.0%–34.3%)
	Mandatory newborn testing; results within 48 hours¶¶	93	81%	(72.3%–88.7%)
Maryland	Opt-in	665	69%	(65.4%–72.8%)
Georgia (20 counties in the Atlanta area)	Opt-in	866	66%	(61.8%–69.6%)
Minnesota (seven counties in the Minneapolis/St. Paul area)	Opt-in	605	62%	(57.5%–65.8%)
California (three counties in the San Francisco area)	Opt-in	575	39%	(34.5%–42.4%)
Oregon (three counties in the Portland area)	Opt-in	498	25%	(21.5%–29.1%)

* Percentages are weighted to reflect all live-born infants and account for sample weights and design.
† Confidence interval.
§ Pregnant women are informed that a human immunodeficiency virus (HIV) test is being conducted as a standard part of prenatal care and that they may refuse it.
¶ Infants are tested for HIV antibodies if the mother was not tested during prenatal care or at delivery. Mother's consent is not required. Neither Connecticut nor New York have data on numbers of newborn infants tested under these laws.
** Policy in effect until August 1999.
†† Policy in effect beginning August 1999.
§§ Pregnant women are required to consent specifically to an HIV test.
¶¶ Policy in effect beginning October 1999.

TABLE 2. Number of women delivering and percentage receiving prenatal HIV testing, by testing approach, year, and province — Canada, 1999–2001

Province	Year	Testing approach	No.	(%)*
Alberta	2000	Opt-out†	37,963	(98)
Newfoundland and Labrador	2001	Opt-out	4,770	(94)
Quebec	1999	Opt-in§	73,781	(83)
British Columbia	1999	Opt-in	41,739	(80)
Ontario	2001	Opt-in	129,758	(54)

* Canadian prenatal human immunodeficiency virus (HIV) testing rates are based on all live-born infants in each province for the year.
† Pregnant women are informed that an HIV test is being conducted as a standard part of prenatal care and that they may refuse it.
§ Pregnant women are required to consent specifically to an HIV test.

Among the three prenatal HIV testing approaches assessed in this report, opt-out voluntary testing and the mandatory testing of newborns appear to be associated with the highest testing rates. On the basis of the chart-review methodology, prenatal testing rates were higher in Tennessee, which uses the opt-out approach, than rates in states using the opt-in approach and similar to rates achieved with mandatory newborn testing in New York during the same time period. A similar trend was observed among Canadian provinces. In New York and Connecticut, mandatory HIV testing of newborns was associated with increases in prenatal testing rates. On the basis of PRAMS data, three of seven states using the opt-in approach achieved lower prenatal HIV-testing rates than states using the opt-out or mandatory newborn testing approaches.

Increases in prenatal HIV-testing rates were noted in states that shifted from an opt-in approach to either an opt-out or mandatory newborn testing approach and were probably associated with a greater likelihood that woman were offered HIV testing during prenatal care. Data from the Perinatal Guidelines Project indicated that the majority of women will accept HIV testing if it is recommended by their health-care provider (*9*). Perinatal HIV experts and professional organizations have advocated streamlining prenatal HIV pre-test counseling and consent procedures to reduce barriers to the offer of testing by health-care providers (*1,2,10*).

The findings in this report are subject to at least seven limitations. First, testing results for each strategy are for all women, and the proportion of HIV-positive women who accepted testing under each strategy is not known. Second, among women who did not receive prenatal testing, the proportion of women who were not tested because they did not seek prenatal care is unknown. Third, among women who did not receive prenatal testing, the proportion of women who were tested at labor and delivery or whose infants were tested at birth is not known. Fourth, maternal self-reported data from

TABLE 3. Percentage of women who responded that they had, had not, or did not know if they had received an HIV test during their most recent pregnancy, by testing approach and state — Pregnancy Risk Assessment Monitoring Survey, United States, 1999

State	Testing approach	No.	Percentage		
			Yes	No	Don't know
Florida	Opt-in*	1,990	81%	13%	6%
New York†	Mandatory newborn testing (1/99–7/99)	758	69%	28%	3%
	Mandatory newborn testing; results within 48 hours of delivery (8/99–12/99)	502	93%	6%	1%
North Carolina	Opt-in	1,770	75%	20%	5%
Illinois	Opt-in	1,994	72%	17%	10%
Colorado	Opt-in	2,039	72%	21%	8%
Arkansas	Opt-out§	1,892	71%	13%	16%
West Virginia	Opt-in	1,327	67%	22%	11%
Oklahoma	Opt-in	1,980	62%	25%	13%
Ohio	Opt-in	1,589	61%	25%	4%

* Pregnant women are required to consent specifically to a human immunodeficiency virus (HIV) test.
† Excludes New York City.
§ Pregnant women are informed that an HIV test is being conducted as a standard part of prenatal care and that they may refuse it.

PRAMS collected 2–6 months after delivery might be subject to recall bias. Fifth, PRAMS data do not indicate whether a prenatal-care provider was aware of the woman's HIV status. Sixth, among the women interviewed in PRAMS, up to 16% (in Arkansas) indicated they did not know if they had been tested. Finally, chart abstraction can document only prenatal HIV testing recorded in maternal medical records; without such documentation, clinicians might not be aware of the need to offer effective perinatal interventions to infected women and their HIV-exposed infants.

This report emphasizes the need for better data to assess perinatal HIV testing rates in the United States. Ongoing, randomized reviews of prenatal, labor/delivery, and pediatric charts, with a sampling framework ensuring that the sample is representative of the population of women delivering, might provide the most valid approach to assessing a state's progress on perinatal HIV testing and prevention. CDC is working with states with high HIV prevalence rates among women of childbearing age and high numbers of pediatric AIDS cases to ensure standardized monitoring of prenatal testing rates. The data suggest that jurisdictions that use an opt-in approach and that have low prenatal HIV-testing rates should reevaluate their approach.

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Influenza Outbreak — Madagascar, July–August 2002

In mid-July 2002, Madagascar health authorities were notified of a substantial number of deaths attributed to acute respiratory illness (ARI) in the village of Sahafata (population: 2,160), located in the rural highlands of Fianarantsoa Province, southeastern Madagascar (Figure 1). This region is approximately 450 km (280 miles) south of the capital Antananarivo. The Madagascar Ministry of Health (MOH) and the Institut Pasteur, Madagascar (IPM) initiated an investigation, which found an attack rate of 70% for ARI, with 27 deaths in Sahafata. Pharyngeal swab specimens were collected from ill persons for viral culture. Of the four influenza A viruses that were isolated at IPM, two were identified

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Medicine and Society - December 2004

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Medicine and Society

Routine Prenatal HIV Testing as a Standard of Care

By Getahun Aynalem, MD, MPH, Peter Kerndt MD, MPH, Kellie Hawkins, MPH

The requirements of pretest counseling and written informed consent are barriers to prenatal HIV testing in the United States, an Institute of Medicine (IOM) panel concluded in 1999. Therefore, the panel recommended that these requirements be eliminated and that prenatal HIV testing become a routine and universal part of prenatal care while still protecting the right of a woman to refuse testing if she chooses not to be tested, ie, "opts out" [1]. The American Medical Association, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists have endorsed the IOM's recommendations [2]. In 2001, the US Public Health Service (USPHS) issued revised guidelines for prenatal HIV testing that stopped short of the IOM recommendations [3]. The Public Health Service advised health care providers to recommend HIV testing to all of their pregnant patients but embraced the requirement for specific written informed consent required by many states. The Health Service also noted, however, that if written consent is deemed a barrier and if state law permits, verbal consent may be enough to perform the test [3].

Following widespread implementation of the USPHS guidelines, the number of HIV tests conducted in prenatal clinics in the United States has risen dramatically, resulting in a sharp decline in the number of perinatally acquired HIV infections [4]. Despite the declines, cases of perinatal HIV transmission continue to occur, largely because of missed opportunities for HIV testing during pregnancy. The estimated 280-370 infants born with HIV infection each year represent populations in which prevention efforts are impeded by lack of timely HIV testing and treatment of pregnant women [5]. These continued infections and changes in public attitude about HIV disease, along with the technological advances in the treatment of the infection, underscore the need for improved strategies that ensure testing of all pregnant women and, if results are positive, treatment to safeguard their health and the health of their infants.

Past controversy about HIV screening of pregnant women has been less related to its scientific aspects than to the social, ethical, and political implications of testing and occurred at the time when no effective preventives were known. In other words, the case of prenatal HIV testing provides a clear example of how nonscientific concerns can trump (whether rightly or wrongly) an otherwise widely accepted, evidence-based strategy. Individuals infected with HIV have often been subjected to prejudice and discrimination, especially early in the epidemic. The high potential for such discriminatory effects was enough to separate HIV screening from other kinds of screening for maternal conditions, such as tests for Rh factor, blood count, glucose levels, rubella immunity, hepatitis B, syphilis, chlamydia, and gonorrhea. Rigid legal requirements for informed consent specific to prenatal HIV testing exist in some states, may require patient notification of the right to refuse testing, and hinder the implementation of universal testing as a routine component of prenatal care [2]. Nonetheless, it has been suggested that mandatory testing for HIV in pregnant women is rational, just as is screening for syphilis. This is in part because the potential harm to the infant is so great (essentially life-or-death) [6], particularly when compared to the relative ease with which treatment of the mother can prevent perinatal HIV transmission.

Mandatory prenatal HIV testing, however, may have negative consequences of its own. First, under mandatory testing, some pregnant women may not seek prenatal care due to a variety of concerns related to testing HIV-positive. Such concerns include the fear of personal illness or death; the fear of losing relationships, jobs, or both; fear of domestic violence [7]; and the fear of financial hardships and stigma that some HIV-positive persons face [8]. Therefore, mandatory testing may reduce the number of pregnant women who seek prenatal care, especially those in high-risk populations [9]. Second, mandatory testing violates patient autonomy, the right to bodily integrity, and the right to make medical decisions about one's care and treatment. It may place individual rights of adults at odds with the state's duty to protect the health and safety of children. Finally, studies have also shown that, given the high levels of acceptance of voluntary HIV testing in the United States, the benefits of mandatory testing are minimal [10]. Therefore, with good reason, a strategy of routine counseling and voluntary testing with the right of refusal has been widely recommended over mandatory testing programs.

Under the "routine counseling and voluntary testing with the right of refusal" strategy, providers of prenatal services can offer HIV testing to all pregnant women under their care. Women have the option to refuse the test if they wish. This strategy can be accomplished in at least 3 ways.

- The first and most widely accepted method is to provide HIV testing only after the woman has been consulted and her informed consent obtained.
- The second method recommends that patients be informed about the provider's intent to perform an HIV test, and only if the woman signs a form refusing the test ("the right of refusal") is the test withheld.

- Lastly, consent of HIV testing may be considered *implied* by a woman's general consent to supply a blood sample for prenatal testing. This method of presumed consent is used in testing for hepatitis B, syphilis, chlamydia, and gonorrhea. Women who seek prenatal care are assumed to consent to routine testing and are not asked for specific verbal or written consent to testing for these diseases.

Studies indicate that all methods of this strategy are cost-effective [11], acceptable to pregnant women, [12] and can achieve the benefits of prenatal HIV screening without violating women's civil liberties [13].

Yet, up to 10 percent of pregnant women may not consent to prenatal HIV-testing [14, 15]. If true, this finding limits the utility of the first 2 methods. Some of the reasons why pregnant women refuse testing include:

- the fear of being stigmatized as sexually promiscuous or as an injection drug user;
- denial about the possibility of being infected;
- fatalism about life;
- fear of rejection leading to loss of emotional and financial support;
- lack of self-perceived risk for HIV infection;
- prior negative HIV test results;
- and lack of spouse approval [14-19].

In our experience in Los Angeles County, 8 percent of pregnant women interviewed refused HIV-testing. Of these, 74 percent were foreign-born, and the most common reasons for refusal were that they had been tested previously (44.6 percent) or were in a monogamous relationship (35.4 percent). Therefore, under the first 2 methods of implementing voluntary testing, some HIV positive women may choose not to be tested. As a result, these women would not receive the treatment and service they need to combat the disease and protect their babies and others against HIV infection. The opportunity to treat the mother early and prevent mother-to-infant transmission will be missed.

The third method—implied consent—has some notable advantages over the previous 2. If consent for HIV testing can be considered *implied* by a woman's general consent to supply a blood sample for prenatal testing and HIV testing is incorporated into the standard battery of prenatal tests, more pregnant women will be tested for HIV. Importantly, at the same time that testing becomes more widespread, the stigma of HIV testing may diminish by elimination of any targeted testing based on appearance, socioeconomic status, and race or ethnicity. For a pregnant woman who was not screened for HIV due to lack of prenatal care, rapid tests during labor and delivery or postpartum should be considered as part of standard obstetrics care to further reduce perinatal HIV transmission.

So, to minimize mother-to-infant HIV transmission and address the social, ethical, and political implications of HIV testing during pregnancy, has the time arrived for health care providers, policy makers, and civil rights advocates to revisit the notion that consent for HIV testing may be considered *implied* by a woman's general consent to supply a blood sample for prenatal testing? Incorporating HIV testing into the standard battery of prenatal tests provides a rational way to implement a sound, evidence-based strategy while addressing some of the critical social and ethical issues surrounding HIV testing.

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Reuters Health
July 4, 2005

Task force urges HIV testing of all pregnant women

NEW YORK (Reuters Health) - The US Preventive Services Task Force has updated its 1996 guidelines for HIV screening, and now recommends that all pregnant women be tested.

That way, HIV-infected pregnant women can start HAART treatment and thereby reduce the risk of vertical transmission of infection to their infants. They can also be advised to avoid breastfeeding, which is known to increase the risk for transmission.

According to its report in the Annals of Internal Medicine, the Task Force continues to recommend screening of adolescents and adults with one or more individual risk factors, including the following:

- Men who have had sex with men after 1975.

- Anyone having unprotected sex with multiple sex partners.

- Past or present injection drug users.

- Men and women who exchange sex for money or drugs or have sex partners who do.

- Individuals whose past or present sex partners were HIV infected, bisexual, or injection drug users.

- Persons being treated for sexually transmitted diseases (STDs).

- Persons with a history of blood transfusion between 1978 and 1985.

Currently, the Task Force does not recommend routinely screening adolescents or adults with no risk factors.

However, they do advise testing persons with no known risk factors but who are seen in high-risk or high-prevalence clinical settings, such as STD clinics, correctional facilities, homeless shelters, TB clinics and clinics with a high prevalence of STDs and those serving men who have sex with men.

SOURCE: Annals of Internal Medicine July 5, 2005.

U.S. Preventive Services Task Force

Screening for Human Immunodeficiency Virus Infection

Release Date: July 2005

Summary of Recommendation / Supporting Documents

Summary of Recommendations

- **The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen for human immunodeficiency virus (HIV) all adolescents and adults at increased risk for HIV infection (go to Clinical Considerations for discussion of risk factors).**

  Rating: A Recommendation.

  Rationale: The USPSTF found good evidence that both standard and U.S. Food and Drug Administration (FDA)-approved rapid screening tests accurately detect HIV infection. The USPSTF also found good evidence that appropriately timed interventions, particularly highly active antiretroviral therapy (HAART), lead to improved health outcomes for many of those screened, including reduced risk for clinical progression and reduced mortality. Since false-positive test results are rare, harms associated with HIV screening are minimal. Potential harms of true-positive test results include increased anxiety, labeling, and effects on close relationships. Most adverse events associated with HAART, including metabolic disturbances associated with an increased risk for cardiovascular events, may be ameliorated by changes in regimen or appropriate treatment. The USPSTF concluded that the benefits of screening individuals at increased risk substantially outweigh potential harms.

- **The USPSTF makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection (go to Clinical Considerations for discussion of risk factors).**

  Rating: C Recommendation.

  Rationale: The USPSTF found fair evidence that screening adolescents and adults not known to be at increased risk for HIV can detect additional individuals with HIV, and good evidence that appropriately timed interventions, especially HAART, lead to improved health outcomes for some of these individuals. However, the yield of screening persons without risk factors would be low, and potential harms associated with screening have been noted (above). The USPSTF concluded that the benefit of screening adolescents and adults without risk factors for HIV is too small relative to potential harms to justify a general recommendation.

- **The USPSTF recommends that clinicians screen all pregnant women for HIV.**

  Rating: A Recommendation.

  Rationale: The USPSTF found good evidence that both standard and FDA-approved rapid screening tests accurately detect HIV infection in pregnant women and fair evidence that introduction of universal prenatal counseling and voluntary testing increases the proportion of HIV-infected women who are diagnosed and are treated before delivery. There is good evidence that recommended regimens of HAART are acceptable to pregnant women and lead to significantly reduced rates of mother-to-child transmission. Early detection of maternal HIV infection also allows for discussion of elective cesarean section and avoidance of breastfeeding, both of which are associated with lower HIV transmission rates. There is no evidence of an increase in fetal anomalies or other fetal harm associated with currently recommended antiretroviral regimens (with the exception of efavirenz). Serious or fatal maternal events are rare using currently recommended combination therapies. The USPSTF concluded that the benefits of screening all pregnant women substantially outweigh potential harms.

U.S. Newswire
July 21, 2003 Monday
SECTION: National Desk, Health Reporter

AOA Supports Immediate HIV Testing and Reporting for Newborns

DATELINE: CHICAGO, Ill., July 21

The American Osteopathic Association's (AOA) House of Delegates voted on Saturday, during their Annual Business Meeting in Chicago, to support the immediate HIV testing and expeditious reporting of results for all newborns whose mothers' HIV status is unknown.

The delegates acknowledged that although there is a national standard of care for routine universal prenatal HIV testing, women have the right of refusal and 25 percent of them choose not to undergo prenatal HIV testing. In addition, 91 percent of all pediatric AIDS cases in the United States result from perinatal transmission from mother to child. However, a study in the New England Journal of Medicine (1998;339;1409) found that 25-40 percent of newborn HIV infections can be prevented if antiretroviral therapy is given to newborns within the first 24-48 hours of life.

The AOA's House of Delegates, comprised of more than 500 osteopathic physicians (D.O.s) and osteopathic medical students from across the country, meets annually in July to set organizational policies and elect new officers.

The AOA represents approximately 49,000 osteopathic physicians (D.O.s), promotes public health, encourages scientific research, serves as the primary certifying body for D.O.s, and is the accrediting agency for all osteopathic medical schools and health care facilities.
http://www.usnewswire.com

CONTACT: Karyn Gianfrancesco of the American Osteopathic Association, 312-202-8042, 800-621-1773, ext. 8042

http://www.kaisernetwork.org/daily_reports/rep_hiv.cfm#19065

Kaiser Daily HIV/AIDS Report
Tuesday, July 29, 2003

2003 National HIV Prevention Conference

Some Pregnant Women Still Go Untested for HIV Despite 1995 CDC Recommendations

More than 20% of pregnant women have never been tested for HIV, despite CDC recommendations released in 1995 calling for all pregnant women to be tested for the virus, the CDC announced yesterday at the 2003 National HIV Prevention Conference in Atlanta, *Reuters Health* reports. **CDC researchers surveyed 346 pregnant women in 2001 and found that 24% had never been tested for HIV** (Rauscher, *Reuters Health*, 7/28). A separate study found that more than 40% of women of childbearing age were unaware that treatment is available to help prevent mother-to-child HIV transmission (Sternberg, *USA Today*, 7/29). This statistic is based on the responses of 55,000 women between the ages of 18 and 44 who participated in the 2001 Behavioral Risk Factor Surveillance System, *Reuters Health* reports (*Reuters Health*, 7/28). According to the CDC, about 300 out of four million infants contract HIV from their mothers each year, compared with between 1,500 and 2,000 infants each year a decade ago (*USA Today*, 7/29). **CDC Director Dr. Julie Gerberding said, "Each case of mother-to-child HIV transmission represents a failure of our public health system. Every pregnant woman should be screened for HIV so that treatment can be offered, if needed, to protect mother and child"** (Gorner, *Chicago Tribune*, 7/29).

'Clear Signs'

CDC researcher Dr. Marc Bulterys said that some of the data presented at the conference indicate "clear signs of the progress we've made and the potential for still greater progress to come." One study conducted by Dr. Guthrie Birkhead of the New York State Department of Health found that HIV testing among pregnant women in the state has increased "sharply," from 64% in 1997 to 94% in 2002. The increase in testing rates paralleled a drop in the rate of vertical HIV transmission in the state -- 10.9% of HIV-positive pregnant women transmitted HIV to their infants in 1997, compared with 3.9% in 2001. Bulterys attributed New York's success to regulatory changes that ensure that women in labor and newborns are tested for HIV. In another study, conducted by Bulterys and members of the Mother Infant Rapid Intervention at Delivery (MIRIAD) group, the OraQuick rapid HIV test was able to deliver accurate results in a little more than one hour for women in labor whose HIV status was previously unknown. The group looked at 3,198 women who delivered in one of 14 hospitals in six U.S. cities. The "quick turn-around time" of the test allowed women in labor to receive antiretroviral treatment to prevent vertical HIV transmission if they tested HIV-positive, Bulterys said. In another study, Delmyra Turpin of the University of Illinois-Chicago examined information for 2,328 HIV-positive pregnant women enrolled in a major national study between 1990 and 2002 found that women were less likely to smoke or use alcohol or hard drugs during pregnancy between 1998 and 2002 "than at any other time during the study," *Reuters*

Health reports. Bulterys said that all of the studies "demonstrat[e] the promise of efforts to reach pregnant women with HIV education and testing" (*Reuters Health*, 7/28).

Reaction

David Harvey, executive director of AIDS Alliance for Children, Youth & Families, said, "Education of health care providers remains the key to further reduction in HIV transmission from mother-to-child. Health care providers must offer an HIV test to every pregnant woman they see and recommend that she take it. There is no excuse for not offering an HIV test." He added, "These studies should not be interpreted to recommend changes in policy, but underscore the need to fully implement universal HIV counseling and voluntary testing." Harvey said, "Universal counseling and voluntary HIV testing works. CDC is wrong to suggest policies are failing or that we should move to more coercive HIV testing policies" (AIDS Alliance for Children, Youth & Families release, 7/28). The CDC in April announced a new HIV prevention strategy, which calls for HIV to be included in routine testing ! for pregnant women and urges local health authorities to make widespread use of a new rapid HIV test (*Kaiser Daily HIV/AIDS Report*, 7/28). Mark Isaac, vice president of the Elizabeth Glaser Pediatric AIDS Foundation, said that the study results "underscore[e] the tremendous need to make HIV testing and counseling a routine part of prenatal care. We've had tremendous success in the last decade in reducing mother-to-child transmission of HIV, but every new case represents a tragedy that could have been averted" (EGPAF release, 7/28).

Reuters Health
July 28, 2003

Curbing perinatal HIV transmission in U.S. still poses challenges

By Megan Rauscher

NEW YORK (Reuters Health) - The number of babies born infected with HIV, the virus that causes AIDS, has fallen sharply in the U.S. over the last 10 years, but an estimated 300 newborns still contract the virus from their mothers each year.

Research presented on Monday during the 2003 National HIV Prevention Conference in Atlanta highlights the significant challenges the U.S. faces in further reducing mother-to-child transmission of HIV, as well promising trends that could signal future progress.

A study from the Centers for Disease Control and Prevention indicates that, despite recommendations supporting voluntary HIV testing of pregnant women as part of standard prenatal care, many pregnant women still go untested.

Among a national sample of 346 pregnant women surveyed in 2001, 24% had never been tested for HIV. In a separate analysis of pregnant women in nine states, the CDC found that HIV testing ranged from 63% in Ohio to 81% in Florida. In this study, African American women younger than age 25 with a high school education or less and who received prenatal care through a public provider or through Medicaid were the most likely to be tested.

In another CDC-led study, 41% of women between 18 and 44 years old were unaware that effective drug treatments to prevent mother-to-infant HIV transmission are widely available in the U.S. This result is based on responses from more than 55,000 women surveyed as part of the 2001 Behavioral Risk Factor Surveillance System.

Speaking to reporters Monday, the CDC's Dr. Marc Bulterys said that despite these challenges, several studies reported at the conference provide "clear signs of the progress we've made and the potential for still greater progress to come."

In one study, Bulterys and members of the Mother Infant Rapid Intervention at Delivery (MIRIAD) collaboration found that the OraQuick rapid HIV test delivered fast accurate results in an average of just over one hour for women in labor whose HIV status was unknown. This study involved 3,198 pregnant women who delivered in one of 14 hospitals in six cities.

"The quick turn-around time with the rapid test allowed most women who tested positive to receive antiretroviral treatment during labor to prevent transmission of the virus to the newborn," Bulterys said.

In another study, this one led by Dr. Guthrie Birkhead of the New York State Department of Health, HIV testing of pregnant women climbed sharply in the state--from 64% in 1997 to 94% in 2002. This increase parallels a significant drop in the rate of HIV transmission to newborns, from 10.9% in 1997 to 3.9% in 2001.

"New York State attributes its success in part to recent regulatory change, designed to ensure HIV tests are given in the delivery settings to all women and newborns for whom prenatal HIV test results are not known," Bulterys said.

Finally, the results of a study, led by Delmyra Turpin of the University of Illinois at Chicago, suggest that pregnant women with HIV are practicing healthier behavior than in the past. They examined information for 2,328 HIV-infected pregnant women enrolled in a major national study during 1990 and 2002 and found that women were less likely to smoke or use alcohol or hard drugs during pregnancy in the period from 1998 to 2002 than at any other time during the study.

"Along with the previous two studies, this research demonstrates the promise of efforts to reach pregnant women with HIV education and testing," Bulterys said.

http://www.chicagotribune.com/features/health/chi-0502140131feb14,1,6144149.story?ctrack=1&cset=true

Chicago Tribune

Saving babies must trump privacy right

Dennis Byrne
Published February 14, 2005

For those looking for hope in the fight against AIDS, there is dramatic news: Infant HIV infection in America has been all but eliminated.

That was the conclusion of a recent New York Times article, which noted that the reduction in the number of HIV-infected newborns nationally dropped to about 200 in 2002, from about 2,000 in 1990. In New York City, cases of infants infected with HIV--the virus that causes AIDS--plummeted from 321 in 1990 to just five in 2003. Illinois reflected that wonderful trend.

Why? More pregnant HIV-infected women are discovering (1) that they are infected and therefore (2) that they are likely to transmit the virus to their newborns, and (3) that they can do something about it. Proving again that information is enabling, the women consented to the application of effective medical treatments. Or, as in New York, the newborn is tested at birth for HIV transmission during the birthing process (i.e. perinatal) in time to administer HIV-fighting drugs.

This comes after the National Institutes of Health's discovery a decade ago that administering HIV-fighting drugs to infected pregnant women can reduce prenatal transmission (i.e. prior to birth) to the fetus by about two-thirds. And the perinatal administration to the newborn of the antiviral drug Nevirapine can produce an even more dramatic reduction--by 89 percent from 1992 to 2001, according to a later study.

By any measure, this is a spectacular medical victory, for children and all of us. It reflects a comprehensive approach to medicine, which includes counseling, follow-up and testing for the presence of HIV antibodies. In New York, that meant, under the 1996 Baby AIDS law, that newborns must be tested (as part of routine tests for other diseases), with or without their mothers' consent, so that life-saving treatment can begin in 12 hours.

The results were dramatic. In February 2002, New York Health Commissioner Antonia Novello announced that the rate of HIV perinatal transmission had

dropped to 3.5 percent from 25 percent. She credited the Baby AIDS law. Few noticed.

In May 2004, New York George Pataki announced a 78 percent decline in infected newborns between 1997 and 2002. Few noticed.

In December 2002, a Centers for Disease Control and Prevention study found that such mandatory testing of newborns was more effective than an "opt-in" approach, in which pregnant women were counseled about the importance of testing, but that was followed by a test only if they consented. Nor was such voluntary testing as effective as an "opt-out" procedure in which the mother is informed that the HIV antibody test would be a part of her routine prenatal tests, unless she decided otherwise. Few noticed.

So why, with such clear knowledge about how to prevent HIV transmission from mother to child, don't we save hundreds more lives by following the science and making prenatal and perinatal testing a routine requirement, as are other tests for diseases? Because some people insist that, in the case of HIV, it is an unconstitutional violation of the woman's and the child's privacy. In other words, a woman's privacy rights trump the child's health or life. Even an Illinois Department of Public Health proposal that only urged Illinois doctors to test high-risk infants was attacked by the American Civil Liberties Union as "an unreasonable, unjustified violation" of the child's and the mother's privacy. So even a newborn's right to privacy is more important than his or her right to a healthy life, or even life itself.

Speaking for this viewpoint was former New York Times columnist Anna Quindlen, who somehow knew that mothers, "with all their many problems," were unsympathetic to the idea. She said routine testing would "drive" women away from appropriate prenatal treatment. " . . . [W]inning their trust and cooperation, not coercing and blindsiding them, is how real change will occur."

Attempts in several states and Congress to make testing a routine fell before what became a well-organized campaign. Editorialists joined in, warning about the impracticality of widespread testing and its lack of "cost-effectiveness." Physicians should only counsel and recommend testing, they said. In Illinois, "opt-out" legislation didn't even get out of committee, based on the argument that there's no "single solution" to pediatric AIDS. As if anyone was arguing there was.

Because HIV transmissions also dropped in "voluntary" testing states, such as Illinois, routine testing clearly is only part of the answer. But how many more newborns could be saved from uncertainty, misery or even death, if HIV testing were routine. Hundreds? Maybe only scores? Probably not worth it, right?

Dennis Byrne is a Chicago-area writer. E-mail: dbyrne1942@earthlink.net



National Review Online
February 4, 2005
http://www.nationalreview.com/comment/lowry200502040752.asp

Civil Libertarians vs. Public Health

A dangerous impulse.

By Rich Lowry

Do we as a society prefer sick or healthy babies? Do we want babies to be infected with a potentially deadly virus or not? The answers seem obvious, but in a decade-long debate, a host of liberal groups, in effect, came down on the wrong side. Fortunately, in New York City — once the epicenter of the epidemic of babies born with HIV — their lunatic obsessions were rejected, and now the scourge of newborns infected with HIV has been all but eliminated.

According to the *New York Times*, in 1990 there were 321 newborns infected with HIV in New York City. In 2003 there were five. A decade ago many pregnant mothers didn't know they were HIV-positive. They weren't urged to get tested, and so they couldn't take drugs that would make it less likely their babies would be infected. Newborns were tested, but — incredibly — in blind tests, meaning the mothers wouldn't be informed of the results. The mother wouldn't know to get treatment for her child or herself.

As AIDS expert Roland Foster points out in a recent study, the most common AIDS-related opportunistic infection is pneumocystis carinii pneumonia. Babies with it generally die in a month. According to a *New England Journal of Medicine* study in the mid-1990s, two-thirds of children with this infection weren't getting treatment, because no one knew they had HIV. It is hard to imagine a more cruelly negligent public-health policy.

Liberal Democratic New York assemblywoman Nettie Mayersohn was appalled — as would be anyone with a wit of common sense — when she learned of the situation. She resolved to pass a law mandating that all newborns be tested and their mothers informed. For this, Mayersohn seemingly bought the enmity of the entire liberal world.

Gay groups, the HIV/AIDS lobby, and the American Civil Liberties Union all opposed her on privacy grounds. As if a newborn has a "right" to have his infection kept from his mother so he can potentially die or get sick. Where does it say anything about that in the Bill of Rights? Feminist groups from NOW to NARAL attacked her for supposedly proposing to violate the reproductive rights of women. Her district office was picketed. Opponents argued that pregnant mothers just couldn't handle testing. "I'm sure we are going to see some women completely freaking out, committing suicide and running away from the whole situation," the director of the HIV Law Project predicted.

"Just the opposite has happened," Mayersohn says. After a three-year fight, her bill passed in 1996. It revolutionized public health in New York. "The way they used to do counseling," she says, "they told women, if you get tested and test positive, you will lose your home and lose your job. After the law passed, they told women, your baby is going to get tested anyway, so if you get tested now, you can do something to keep your baby from being born HIV-positive."

More mothers and babies now get care. An HIV-positive mother has roughly a 25-percent chance of delivering a baby infected with HIV. If she takes the right drugs during pregnancy she can drastically diminish those odds. An HIV-positive mother can also pass the infection to her uninfected baby during breast-feeding. If she knows she's infected, she can avoid that. Finally, if a baby is infected with HIV, he can be treated early with drugs that might wipe out the infection.

Then-Rep., now Sen. Tom Coburn pushed legislation similar to Mayersohn's at the federal level in the 1990s, but was frustrated by the same forces that opposed Mayersohn. Consequentially, the testing policy varies from state to state. Nationally, the rate of infants infected with HIV has declined, but it has not been stamped out. California — where lunatic obsessions still reign supreme — has resolutely resisted the New York approach. In 2002, the *Los Angeles Times* reported that cases of HIV among children were actually increasing.

So let's ask one more time: Do we want healthy babies or not?

— Rich Lowry is author of *Legacy: Paying the Price for the Clinton Years.*

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The New York Times
June 25, 1995, Sunday, Late Edition - Final
SECTION: Section 4; Page 14

AIDS Babies Deserve Help, Now

Hundreds of babies infected with the AIDS virus will continue to go undetected and untreated every year unless Congress or New York State deal with this vexing public health problem. The State Legislature, immobilized by a fierce clash between those who want mandatory testing of all newborns and those who prefer a voluntary approach, has been unable to agree on a solution. Congress, knocked off course when the same fierce clash stopped a Federal survey of infected babies, has yet to take action.

Both bodies have a responsibility to get on with the job. It is simply irresponsible to let newborn babies go untreated while arguing over the mechanics of how to help them.

The need for a vigorous response is clear. Women are becoming infected with the AIDS virus in rising numbers, and about 7,000 of them give birth each year. Many pass the virus on to their babies, either in the womb or during birth. Some 1,000 to 2,000 babies are infected this way each year, with New York State alone accounting for roughly a quarter of the total. Some of the infected babies are detected through voluntary blood tests on the mothers or their newborns. The rest go undetected and untreated until they become sick, when it is too late to offer them the best shot at a longer life.

Medical science knows quite well how to alleviate this damage. The best solution by far is to identify and treat the expectant mother before her child is born. One of the few bright spots in the battle against AIDS was the discovery last year that treating a pregnant woman with the drug AZT can greatly reduce the chances that she will pass the AIDS virus on to her child, saving most of the babies from infection.

Unfortunately, large numbers of women never come near a clinic for prenatal care and many of those who do come in for such care never

get tested for the AIDS virus. So a fallback solution is to identify all infected newborns as early as possible, through blood tests, so that they can be closely monitored and treated. Doctors have no way to cure these infected babies, but they can ward off many of the infections that typically kill them, thus prolonging and improving the quality of their lives.

Although the medical solutions are in hand, they are not in fact being broadly applied. In New York State, for example, clinics try, with widely disparate vigor and success, to get women to agree to be tested during pregnancy or at birth and to allow their babies to be tested. But surveys suggest most of the infected babies are missed. A more vigorous effort is clearly needed.

Unfortunately, the State Legislature may be headed for another stalemate. The Senate has passed a bill to require mandatory testing of all newborns and mount a more aggressive voluntary testing program aimed at pregnant women. The new voluntary approach would make it harder and less likely for women to decline testing. But the Assembly has taken no action yet and has only four days before adjournment. Its leaders have traditionally opposed mandatory testing but seem inclined to accept a more vigorous voluntary effort for both pregnant women and newborns.

Either approach would be better than the status quo. This page has long endorsed mandatory tests for newborns on the ground that the health of the baby is more important than any privacy risk to the mother. But there is virtually no political appetite for imposing mandatory tests on pregnant women, so a strong voluntary approach is the only feasible alternative.

The best solution would be a national policy insuring that all infected babies are identified for monitoring and treatment. Representative Gary Ackerman, Democrat of New York, and Representative Tom Coburn, Republican of Oklahoma, will unveil an amendment this week that would require states, as a condition for receiving certain Federal AIDS funds, to test all newborns whose risk of infection has not been determined through voluntary testing of the expectant mother. That approach would provide a needed incentive for the states to identify and help these neglected babies.

ORGANIZATION: OPPOSED TO BABY AIDS PREVENTION PROPOSAL

July 7, 1995

The Honorable Tom Coburn
United States House of Representatives
Washington, DC 20515

Dear Representative Coburn :

We, the undersigned national minority organizations and local HIV/AIDS service providers concerned about the health and welfare of people of color throughout the United States, are writing to you today to express our unequivocal opposition to the efforts currently being undertaken in Congress to mandate HIV testing of pregnant/postpartum women and newborns. We are also writing to express our opposition to the recent proposal to amend H.R. 1872, **the Ryan White CARE Act Amendments of 1995**, with a provision which would require states to establish and implement mandatory HIV testing of newborns, as a condition for receipt of Ryan White CARE Act funds.

NATIONAL MINORITY AIDS COUNCIL

1931 13TH STREET, NW
WASHINGTON, DC
20009-4432
TEL 202-483-NMAC (6622)
FAX 202-483-1135
E-MAIL NMAC1@aol.com

We share the public health goal of preventing and reducing the perinatal transmission of HIV infection from infected mother to newborn. However, we are particularly concerned about the adverse impact of such an amendment because of the trends of HIV infection among women of color. Rates of HIV infection and AIDS among all women are increasing. Despite geographic variations, women of color are disproportionately affected by HIV/AIDS. African American and Latina women are most severely impacted: while together they represent 21% of the total population of women in the United States, they account for 75% of the cumulative AIDS cases reported among women.

As organizations promoting the health and welfare of people of color we must uniformly oppose any and all such measures which would mandate HIV testing of pregnant and post partum women, and or their newborns. We recognize the importance of preventing perinatal HIV transmission and of identifying HIV infected newborns and providing them with early medical care and treatment. We concur that these are important public health goals. However testing newborns for HIV infection will not serve to prevent perinatal transmission. We believe that the inclusion of such measures in the Ryan White CARE Act undermines the intent of the Act, which is to provide vital HIV/AIDS related medical, treatment and support services to all people living with HIV/AIDS throughout the country.

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TREATMENT CORP.
BROOKLYN, NY
VIVIAN TORRES
ST. COLUMBA NEIGHBORHOOD CLUB
NEWARK, NJ

EXECUTIVE DIRECTOR
PAUL AKIO KAWATA



Such testing of newborns will not assure access to care. These public health goals will be more effectively and efficiently achieved through the provision of comprehensive prenatal care to all women. The prenatal care should include counseling about the risks of HIV infection and the availability of voluntary HIV testing, the provision of information about the options available to prevent perinatal HIV transmission, and access to treatment and care for both the woman and her newborn.

Studies show that when a pregnant woman's health care provider talks with her about the HIV test and what it means for her and her baby, most women choose to be tested and then to be treated as their doctor recommends. The best way to ensure that HIV infected newborns receive appropriate treatments including PCP prophylaxis is to educate and counsel parents about the treatment options available to delay onset and progression of HIV disease. We support this approach along with the provision of access to needed treatment and care.

We are committed to working with Congress and the appropriate Public Health Service agencies to ensure that sound public health approaches are used to prevent HIV infection among women and perinatal transmission from mother to newborn. While we support the reauthorization of the Ryan White CARE Act, we cannot support a provision for mandatory HIV testing. We hope you will join us in our opposition to mandatory HIV testing.

Thank you for your consideration of this important issue. Please contact Miguelina Maldonado, Director of Government Relations and Policy, of the National Minority AIDS Council, if you have any questions or would like to discuss this matter further. She may be reached at (202) 483-6622.

Respectfully,

Tucson AIDS Project , Tucson , Arizona

CODAC Behavioral Health Services, , Tucson , Arizona

Northeast Arkansas Regional AIDS , , Arkansas

Mallalieu Black Community , Fort Smith , Arkansas

Mobililization Against AIDS , San Francisco , California

Women's AIDS Network , San Francisco , California

National Asian Pacific American , Los Angeles , California

Asian Community Mental Health , Oakland , California

AIDS Service Center , Altadena , California

AIDS Project Los Angeles , Los Angeles , California



San Francisco AIDS Foundation , San Francisco , California

AIDS Legal Referral Panel , San Francisco , California

Living Well Project/ Asian Pacific , San Francisco , California

Filipino Task Force on AIDS , San Francisco , California

Santa Cruz AIDS Project/Proyecto , Santa Cruz , California

AIDS Medicine & Miracles , Boulder , Colorado

AIDS Legal Network for Hartford , Hartford , Connecticut

Whitman Walker Clinic , Washington , DC

National Black Women's Health , Washington , DC

NEA Health Information Network , Washington , DC

National Puerto Rican Coalition , Washington , DC

National Latino/Latina Lesbian & Gay , Washington , DC

National Task Force on AIDS , Washington , DC

National Minority AIDS Council , Washington , DC

Center for Women Policy Studies , Washington , DC

AIDS Treatment Initiatives , Atlanta , Georgia

AIDS Education Services for Minorities , Atlanta , Georgia

Feminist Women's Health Center , Atlanta , Georgia

Sisterlove , Atlanta , Georgia

Papa Ola Lokahi , Honolulu , Hawaii

Life Foundation , Honolulu , Hawaii

Rally to Life , Chicago , Illinois

AIDS Southern Kentucky, Inc. , Bowling Green , Kentucky

South Cove Community Health Center , Boston , Massachusetts

Unitarian Univeralist Association of , Boston , Massachusetts

Healthy Boston Coalition for Gay, , Boston , Massachusetts

Fenway Community Health Center , Boston , Massachusetts

Action for Boston Community Health , Boston , Massachusetts

Community Research Initiative of , Boston , Massachusetts



The Multicultural AIDS Coalition, Inc., Boston, Massachusetts

Community Health And Prevention , Leominster, Massachussetts

Latino Family Services, Inc., Detroit, Michigan

Minnesota American Indian AIDS , Minneapolis, Minnesota

Indian Health Board of Minneapolis , Minneapolis, Minnesota

Community Outreach for Risk , St. Louis, Missouri

Planned Parenthood of Missoula , Missoula, Montana

FDH & Associates , Billings, Montana

Yellowstone AIDS Project , Billings, Montana

PRIDE , , Montana

South Asian Counseling & , Jersey City, New Jersey

Women and AIDS Resource Center , New York, New York

Asian Pacific Islander Coalition on , New York, New York

Hispanic AIDS Forum, Inc., New York, New York

Family Health Project, Inc., New York, New York

Latino Commission on AIDS , New York, New York

Centro Civico of Amsterdam, Inc., Amsterdam, New York

Haitian Coalition on AIDS , New York, New York

Action for a Better Community , Rochester, New York

Urban League of Westchester , White Plains, New York

Gay Men's Health Crisis , New York, New York

South Bronx Ecumenical AIDS , Bronx, New York

East New York/Brownsville , Brooklyn, New York

New Hope Guild Center of East New , Brooklyn, New York

Staten Island HIV CARE Network , Staten Island, New York

Help/Ayuda Program , New York, New York

AIDS Regional Interfaith Network , Oklahoma City, Oklahoma

Indian Health Care Resources Center , Tulsa, Oklahoma

South Central Pennsylvania AIDS , Harrisburg, Pennsylvania



Philadelphia AIDS Consortium , Philadelphia , Pennsylvania

Comite Accion Social , Mayaguez , Puerto Rico

South Carolina AIDS Education , Columbia , South Carolina

Informe SIDA-ALLGO , Austin , Texas

International District Community , Seattle , Washington

AIDS Housing of Washington , Seattle , Washington

Institute for Child & Family , Milwaukee , Wisconsin

WHY ROUTINE TESTING WORKS AND CURRENT TESTING STRATEGIES DO NOT

Since the first diagnostic test for HIV antibodies was developed in the 1980s, screening for HIV has been treated differently than testing for any other medical condition, infection or disease. Due to fears of violence, discrimination, and other acts of rejection that could deter those at risk from seeking testing, laws and policies were enacted to prohibit mandatory testing or even testing without extensive pre-test counseling. This counseling included prevention education and warnings about the potential negative social consequences of being diagnosed.

While this approach may have been important to ease the anxiety of many of those at risk at the onset of the epidemic before effective treatments were available and much was unknown about the disease, the unintended consequence has been the creation of deterrents and stigma surrounding HIV testing.

Pre-test counseling for HIV can take more than 20 minutes, limiting the number of tests that can be administered. While some argue that such counseling is important for prevention, studies have found that even with pre-test prevention counseling, repeat testers are more likely to report recent risk behavior and to acquire HIV. Furthermore, the stigma associated with requesting HIV testing has deterred many from requesting testing and the extensive counseling required has discouraged many medical providers from suggesting testing to those without obvious risk factors.

CDC estimates that currently 1 to 1.2 million people in the United States are infected with HIV, and of these, 252,000-312,000 (roughly a quarter) are undiagnosed. This undiagnosed group is of great concern because they are not able to take advantage of medical treatment and because infections transmitted by those who are unaware that they are HIV positive are believed to account for more than half of new HIV infections each year. When people know their status, they are more likely to protect their partners from infection. Many persons with HIV infection visit health care settings in the years before their diagnosis, yet they are infrequently tested for HIV.

For these reasons, efforts to increase HIV testing and diagnosis should be essential components of HIV prevention and treatment strategies.

This section contains additional background on this issue including the current HIV counseling forms.

County of Los Angeles, Department of Health Services, Office of AIDS Programs And Policy

CONSENT FOR HIV TESTING AND REFERRALS **DHA/OA Laboratory/Sticker Number:** _____

I have discussed this testing procedure with a Certified HIV Counselor or Medical Care Provider. I had the chance to ask questions, and these questions were satisfactorily answered for me. I understand that a sample of my blood and/or other bodily fluids will be taken and that the sample will be tested for antibodies to the Human Immunodeficiency Virus (HIV), the virus that causes Acquired Immune Deficiency Syndrome (AIDS). According to Health and Safety Code section 120775, "HIV test" means any clinical test, laboratory or otherwise, used to identify HIV, a component of HIV, or antibodies or antigens to HIV. I was told about the meaning and the limits of the test. I understand that if I have been recently infected with HIV, it may take some time before a test will show the infection. For this reason, I may have to repeat the test. I understand that the test's accuracy and reliability are not 100% certain.

Benefits of the test include having test results that can help me make better decisions about my health care and my personal life. The test results can help my doctor and me make decisions concerning medical treatment. If the results are positive, I know that I can infect others and I can also act to prevent this. Potential risks of the test include psychological stress while awaiting the results, and distress if the results are positive.

I understand that in the event I test positive for HIV, the virus that causes AIDS, I will receive customized medical care referrals (based on the information I provide) at the time of disclosure of HIV positive status. I am aware that it is my choice whether or not I seek the suggested referral services from the providers recommended to me. I understand that I may be eligible to receive Ryan White Comprehensive AIDS Resource Emergency (CARE) Act-funded medical and/or social services, regardless of whether or not these services are provided by one of the agencies recommended to me.

I understand that if I choose to test using a rapid HIV testing device, I will receive my initial HIV test result before I leave today. I am aware that a negative test result does not require confirmation. I understand that a reactive or preliminary positive rapid HIV test result must be confirmed by a laboratory based test. I consent to give a blood or oral fluid sample for this confirmatory test if my initial test result is reactive or preliminary positive.

I have been informed that these referrals and subsequent follow-up, if any, may be the result of the County's new HIV/AIDS Information Resources System (HIRS), which involves collecting personal demographic information (gender, ethnicity, geographic location, age and language needs) for all clients who test confidentially. If a client tests for HIV anonymously, such information is not required.

I have been informed that all personal information disclosed remains confidential and secure and can only be accessed by my primary care provider (such as a physician, case manager, case worker, etc.). This information will help my provider deliver unique referrals that meet my geographic, cultural and language needs.

By my signature below, I acknowledge that I have read and understand the information in this form. Also, I acknowledge that I have been given information concerning the benefits and risks, and I consent to be tested for HIV. I also realize that I have a right to receive a copy of this consent form.

Print Client Name	Client Signature	Date
Print Guardian/Other Name (if applicable)	Guardian/Other Signature	Date
Print Witness Name	Witness Signature	Date

Last 4 Digits of Social Security Number (SSN)
_ _ _ _

Approval Valid for Enrollment
11/12/05 To 11/12/06
Institutional Review Board
Department of Health Services

CONSENT TO BE CONTACTED GIVEN: YES [ ] NO [ ]

FOR CONFIDENTIAL TESTING SERVICES ONLY:
In the event that I do not return for my results, I may be contacted by _____ to reschedule my appointment.
(Agency)

Contact Information Must Be Supplied If Consent To Be Contacted Is Given

Name (as indicated on ID)	Home Phone	Alternate Phone/E-mail	
Address	City	State	Zip
Other specific information (additional password/name)			

NOTE TO AGENCY STAFF: After this consent is signed and dated, a copy must be given to the client and the original placed in the client's chart.

9/23/0

Condado de Los Angeles, Departamento de Servicios de Salud, Oficina de Programación y Política del SIDA
FORMA DE CONSENTIMIENTO PARA LA PRUEBA DEL VIH Y PARA REFERENCIAS

DHA/OA Laboratory/Sticker Number____

He discutido el procedimiento de la prueba con un Consejero Certificado del VIH o un miembro del personal de cuidado médico. Tuve la oportunidad de hacer preguntas las cuales fueron contestadas satisfactoriamente. Entiendo que me sacarán una muestra de sangre y/u otro liquido de mi cuerpo para buscar los anticuerpos del Virus de Inmunodeficiencia Humana (VIH), el agente que causa el Síndrome de Inmuno Deficiencia Adquirida. De acuerdo al Código de Salud y Seguridad, sección 120775, " la prueba del VIH " quiere decir cualquier prueba clínica, de laboratorio u otro método usado para identificar el VIH, un componente del VIH o anticuerpos o antígenos del VIH. He sido informado(a) acerca del significado y los límites de la prueba. Yo entiendo que si he sido infectado(a) recientemente con el VIH, puede pasar un tiempo antes de que la prueba detecte la infección. Por esta razón, puede que tenga que repetir la prueba. También entiendo que la confiabilidad y la exactitud de la prueba no son 100% seguras.

Los beneficios de la prueba incluyen el tener resultados que me puedan ayudar a tomar mejores decisiones acerca del cuidado de mi salud y mi vida personal. Los resultados de la prueba me pueden ayudar a mí y a mi doctor a tomar decisiones acerca de mi tratamiento médico. Si mis resultados son positivos yo sé que puedo infectar a otros y que puedo evitar que esto suceda. Los riesgos potenciales de la prueba incluyen estrés sicológico mientras espero recibir mis resultados y aflicción si mis resultados son positivos.

Yo entiendo que en caso de que reciba un resultado positivo para el VIH, el virus que causa el SIDA, recibiré referencias personalizadas para mi tratamiento médico (basadas en la información que provei) en el momento que se me de a conocer que soy VIH positivo. Estoy consciente de que es mi opción el buscar los servicios a los cuales soy referido(a) con los proveedores que me fueron sugeridos. Yo entiendo que es posible que yo sea elegible para recibir servicios médicos o sociales cubiertos bajo la Acta Ryan White Comprehensive AIDS Resource Emergency (CARE) a pesar de que estos servicios sean o no proveidos por una de las agencias que se me ha recomendado.

Yo entiendo que si elijo tomar la prueba para el VIH con un dispositivo de prueba rápida, recibiré hoy mi resultado inicial de la prueba del VIH antes de que me vaya. Estoy enterado que un resultado negativo de la prueba no requiere una confirmación. Yo entiendo que un resultado positivo reactivo o preliminar de la prueba rápida del VIH tendrá que ser confirmada por una prueba por un laboratorio. Yo consiento dar una muestra de sangre o flúido oral para esta prueba confirmativa si mi resultado de la prueba inicial es reactivo o preliminar positivo.

He sido informado(a) de que estas referencias y siguientes citas, si suceden, pueden ser el resultado del nuevo Sistema de Información de Recursos del VIH/SIDA del Condado conocido como HIRS, el cual incluye la colección de información demográfica personal (sexo, grupo étnico, lugar geográfico, edad y necesidades lingüísticas) de todos los clientes que toman la prueba confidencial. Si un cliente se hace la prueba del VIH anónima, tal información no es requerida.

He sido informado(a) que toda la información personal provista permanecerá confidencial y segura y solamente puede ser accesible a mi proveedor de salud principal (como un médico, manejador de casos, trabajador de casos, etc.) Esta información le ayudará a mi proveedor a proporcionarme con referencias especializadas que satisfagan mis necesidades geográficas, culturales y lingüística

Al firmar abajo, yo reconozco que he leído y comprendo la información en esta forma. También reconozco que se me a dado información sobre los beneficios y riesgos y doy consentimiento para que se me haga la prueba del VIH. Asimismo entiendo que tengo el derecho de recibir una copia de esta forma de consentimiento

Nombre del Cliente en Letra de Molde	Firma del Cliente	Fecha
Nombre del Guardián/Otro Nombre (si aplica)	Firma del Guardián/Otra Firma	Fecha
Nombre del Testigo en Letra de Molde	Firma del Testigo	Fecha

Últimos 4 dígitos del Número de Seguro Social (SSN)

CONSENTIMIENTO PARA SER CONTACTADO DADO: SI [ ] NO [ ]

Approval Valid for Enrollment
From 11/13/06 To 11/12/07
Institutional Review Board
Department of Health Services

SOLAMENTE PARA SERVICIOS DE PRUEBAS CONFIDENCIALES:
En caso de que no regrese por mis resultados, _____ puede ponerse en contacto conmigo para volver a hacer una cita.
(Agencia)

Si el Cliente dio Consentimiento para ser Localizado se Debe Suplir la Siguiente Información

Nombre (como se indica en la identificación) No. De Teléfono de Casa Otro Teléfono/E-mail

Domicilio Ciudad Estado Zona Postal Otra Información Específica Adicional

NOTE TO AGENCY STAFF. After this consent is signed and dated, a copy must be given to the client and the original placed in the client's ch

9/23/20

AIDS Healthcare Foundation Prevention and Testing Department

Request Form for Confidential HIV Test Results

Chart #

I _____ was provided my test result on _____ at the following test site:

TEST RESULT

- ☐ Weho OTC
- ☐ Hollywood OTC
- ☐ N. Hollywood OTC
- ☐ Westside Clinic
- ☐ JTP #_____
- ☐ Downtown Clinic
- ☐ Hollywood Clinic
- ☐ Mobile _____
- ☐ CSV _____

I understand that an HIV negative (non-reactive) test result means that HIV antibodies were not detected at the time of testing. This could mean that I have not been exposed to HIV or my immune system has yet to develop antibodies and that I am in the "window period". The "window period" refers to the point of exposure to HIV and the time it takes your body to produce the antibodies to HIV. It usually takes the body 2-12 weeks and in some cases up to six months to produce detectable levels of antibody. I understand that an HIV positive (reactive) test result means that I am HIV infected. It does not mean that I am certain to get AIDS. I have been advised to seek further medical evaluation to monitor my health status.

Furthermore, I understand that an indeterminate test result means that I am neither HIV negative or HIV positive. This result could be due to reasons other than HIV. Or, I could be in the "window period" and there are not enough antibodies present to give an HIV positive result. In this case, I may need a follow-up test.

Disclaimer: This HIV antibody test result indicates whether anitbodies to HIV were present at the time the specimen was tested. If the result indicated on the slip is HIV negative (non-reactive) or indeterminate, it may not reflect the individual's current HIV status. Unless an individual's name clearly appears in the appropriate space provided, the test result cannot be attributed to the bearer of this slip.

_____ Signature of HIV Testing Counselor

_____ Signature of Client Tested

☐ Check if client did not want copy

_____ Printed name of HIV Testing Counselor

_____ Printed name of Client

Conversion of HIV test results from anonymous to confidential

I _____ do hereby give my permission to the staff of AIDS Healthcare Foundation to change my HIV test results from anonymous to a confidential status.

The difference between anonymous and confidential has been explained to me and I had the opportunity to ask questions and those questions have been answered.

I understand that in order to change my HIV test results from anonymous to confidential I must give my full legal name to the staff of AIDS Healthcare Foundation I understand that by doing so, the eight-digit anonymous code assigned to me at the time of anonymous testing will be replaced with my legal name and that my legal name will appear on the converted confidential test result form.

I further understand that upon completion of the change of my anonymous HIV test result to a confidential status, I will be provided the original confidential laboratory result form and that AIDS Healthcare Foundation will keep a copy. It was explained to me that AIDS Healthcare Foundation staff would retain their copy under the original eight-digit code assigned to me at the time of initial anonymous HIV testing.

AIDS Healthcare Foundation staff may also include a phone number on the confidential form. This phone number will be used if I fail or forget to pick-up my HIV results. AIDS Healthcare Foundation assures that trained staff will use discretion and will not disclose the purpose of the call to anyone other than the person on the testing form.

Counselor Signature:	Client Signature:
Print Counselor Name:	Print Client Name:
Date:	Phone Number:

F:\Divisions\Prevention Services\Risk Reduction\Common\1 Rumanes Files\HIRS-HITS\Anonymous to Confidential Form.doc

C:\Documents and Settings\Susannahf\My Documents\SUSANNAH\HIRS\Anonymous to Confidential Form REVISED 7-2004.doc

County of Los Angeles, Department of Health Services, Office of AIDS Programs And Policy

AUTHORIZATION to RELEASE and SHARE GENERAL MEDICAL INFORMATION

DHA/OA Laboratory/Sticker Number_____

I, _____, authorize _____(agency), as part of a cooperative group of Los Angeles County, Department of Health Services, Office of AIDS Programs and Policy-contracted agencies, to release/share my information among the participating agencies for the express purpose of receiving or gaining access to services related to my current or future needs. This information will include services I have received, my physical condition (i.e. viral loads and CD4 counts), my eligibility for various programs and services, name, date of birth, gender, race/ethnicity, and last 4 digits of my SSN.

I agree to allow all of the OAPP-contracted providers to conduct program evaluations and quality management activities and to exchange my information among the participating cooperative group. I understand that this information is necessary to appropriately coordinate and evaluate the HIV prevention and care services provided to me. I understand that I am not required to sign this authorization in order to receive services.

I understand that this authorization may be revoked at any time by signing the cancellation line at the end of this document. Otherwise, this authorization is valid as long as I am receiving services from any of the cooperative agencies. I may also add other specific agencies to this form by listing them and signing below. I understand that I have a right to receive a copy of this authorization form as well as the attached list of current OAPP-contracted providers who participate in the HIV/AIDS Information Resources System (HIRS) cooperative group.

Print Client Name	Client's Signature	Date
Print Agency Representative's Name	Representative's Signature	Date

I wish to add the following specific agencies to this authorization:

1. _____
2. _____
3. _____

Print Client Name	Client's Signature	Date
Print Agency Representative's Name	Representative's Signature	Date

I wish to cancel this authorization.

Print Client Name	Client's Signature	Date
Print Agency Representative's Name	Representative's Signature	Date

NOTE TO AGENCY STAFF: After this authorization is signed and dated, and a comprehensive list of "Prevention and Care Contractors" is initialed, a copy of each must be given to the client and the originals placed in the client's chart. **12/17/2003**

Department of Health Services, Public Health

HIV COUNSELING INFORMATION FORM

Office of AIDS Programs and Policy

Test Date: Risk Assessment Date: R.A./Test Sticker No.: *(adhere lab sticker here)*

Counselor Name: Counselor ID:

Alternative billing: *(mark all that apply)* ☐ No billing to OA ☐ Risk Assessment ☐ Disclosure ☐ Post Disclosure ☐ Laboratory Work

Detuned: *(studies only)* ☐ DTR (recent) ☐ DTL (long standing) ☐ DTNT (not tested)

CLIENT DEMOGRAPHIC INFORMATION

Provider/Agency ID: _____ Site Code:_____ HIRS Client ID: _____

ID No./Type (CA DL, Photo ID Card, etc.):_____ ☐ Identity verified Name: First Initial: _____ Last Name: _____

Gender: ☐ M ☐ F Transgender: ☐ M/F ☐ F/M ☐ Other _____ DOB: _____ Resident Zip Code:_____ County: _____

Race/Ethnicity ☐ White ☐ African American ☐ Latino/Hispanic ☐ Asian/Pacific Is ☐ Am. Indian/AK Native Other:_____ State: ___

☐ Pregnant ☐ Homeless

Form: ☐ Consent ☐ Release ☐ Release Revoked Date _____

Sexual orientation: *(mark one)* ☐ Heterosexual(straight) ☐ Bisexual ☐ Gay, lesbian, queer, or homosexual ☐ Client doesn't know ☐ Other, specify:_____

Referred by: ☐ HIV+ Partner ☐ PCRS/Partner Notification ☐ Internet ☐ Media ☐ HIV Education Program ☐ Other AIDS Agency ☐ Outreach Program ☐ AIDS Telephone Hotline ☐ Friend/Relative ☐ Social Services ☐ Mental Health ☐ M.D./Health Clinic ☐ Alcohol/Drug Program ☐ Other outreach worker ☐ No identifiable referral source

CLIENT SEXUAL RISK HISTORY

Total number of sex partner(s): *(last 2 years/last result)*

Male sex partner(s)

Partner(s): *(mark one)*	Sexual activity:	Yes	No	TFC	Frequency of barrier use: Never	Sometimes	Always
☐ no partners	Oral	☐	☐		☐	☐	☐
☐ one or more	Vaginal	☐	☐		☐	☐	☐
☐ declined/refused	Anal insertive	☐	☐		☐	☐	☐
	Anal receptive	☐	☐		☐	☐	☐

Female sex partner(s)

Partner(s): *(mark one)*	Sexual activity:	Yes	No	TFC	Frequency of barrier use: Never	Sometimes	Always
☐ no partners	Oral	☐	☐		☐	☐	☐
☐ one or more	Vaginal	☐	☐		☐	☐	☐
☐ declined/refused	Anal insertive	☐	☐		☐	☐	☐

Transgendered partner(s)

Partner(s): *(mark one)*	Sexual activity:	Yes	No	TFC	Frequency of barrier use: Never	Sometimes	Always
☐ no partners	Oral	☐	☐		☐	☐	☐
☐ one or more	Vaginal	☐	☐		☐	☐	☐
☐ declined/refused	Anal insertive	☐	☐		☐	☐	☐
	Anal receptive	☐	☐		☐	☐	☐

Sex with sex worker(s)/prostitute(s)

Partner(s): *(mark one)*	Sexual activity:	Yes	No	TFC	Frequency of barrier use: Never	Sometimes	Always
☐ no partners	Oral	☐	☐		☐	☐	☐
☐ one or more	Vaginal	☐	☐		☐	☐	☐
☐ declined/refused	Anal insertive	☐	☐		☐	☐	☐
	Anal receptive	☐	☐		☐	☐	☐

Gender: ☐ M ☐ F ☐ T-M/F ☐ T-F/M ☐ Other ☐ DK

Sex partner(s) who injected drugs or other substances

Partner(s): *(mark one)*	Sexual activity:	Yes	No	TFC	Frequency of barrier use: Never	Sometimes	Always
☐ no partners	Oral	☐	☐		☐	☐	☐
☐ one or more	Vaginal	☐	☐		☐	☐	☐
☐ declined/refused	Anal insertive	☐	☐		☐	☐	☐
	Anal receptive	☐	☐		☐	☐	☐

Gender: ☐ M ☐ F ☐ T-M/F ☐ T-F/M ☐ Other ☐ DK

HIV-Infected sex partner(s)

Partner(s): *(mark one)*	Sexual activity:	Yes	No	TFC	Frequency of barrier use: Never	Sometimes	Always
☐ no partners	Oral	☐	☐		☐	☐	☐
☐ one or more	Vaginal	☐	☐		☐	☐	☐
☐ declined/refused	Anal insertive	☐	☐		☐	☐	☐
	Anal receptive	☐	☐		☐	☐	☐

Gender: ☐ M ☐ F ☐ T-M/F ☐ T-F/M ☐ Other ☐ DK

☐ **Mark if client knew partner's HIV positive status prior to sexual contact.**

(Females Only) Male partner(s) who has had sex with a male

Partner(s): *(mark one)*	Sexual activity:	Yes	No	TFC	Frequency of barrier use: Never	Sometimes	Always
☐ no partners	Oral	☐	☐		☐	☐	☐
☐ one or more	Vaginal	☐	☐		☐	☐	☐
☐ declined/refused	Anal receptive	☐	☐		☐	☐	☐

Gender: ☐ M ☐ T-M/F ☐ T-F/M ☐ Other ☐ DK

Time Frame Code **(TFC):** *(studies only)* **6** = within past 6 mo **1** = within past 12 mo **2** = within past 2 yrs **+** = greater than 2 yrs **9** = unknown
***** = declined/refused

DRUG & SUBSTANCE USE HISTORY *(last 2 years/last result)*

Drugs & Substances used: ☐ No alcohol or drug used ☐ Declined/Refused

Drugs Used *(mark all that apply)*	Usage Y	N	D	TFC	Injected *yes*	Frequency used with sex: Never	Rarely	Sometimes	Usually
Alcohol	☐	☐	☐		☐	☐	☐	☐	☐
Marijuana *(pot,grass,weed,hash)*	☐	☐	☐			☐	☐	☐	☐
Heroin,etc. *(junk,skag,smack,H)*	☐	☐	☐		☐	☐	☐	☐	☐
Barbiturate/ Tranquilizers	☐	☐	☐		☐	☐	☐	☐	☐
Crack *(rock)*	☐	☐	☐		☐	☐	☐	☐	☐
Amphetamine *(crank,crystal,tina)*	☐	☐	☐		☐	☐	☐	☐	☐
Cocaine *(powder)*	☐	☐	☐		☐	☐	☐	☐	☐
Nitrate/nitrite *(poppers,rush)*	☐	☐	☐			☐	☐	☐	☐
Ecstasy *(MDMA,Adam, E, X)*	☐	☐	☐		☐	☐	☐	☐	☐
GHB *(liquid ecstasy,gina,G)*	☐	☐	☐		☐	☐	☐	☐	☐
Ketamine *(special K, K)*	☐	☐	☐		☐	☐	☐	☐	☐
Viagra *(Cialis, Levitra, Meltabs, Caverta, Generic: Viagra, Cialis, & Levitra)*	☐	☐	☐			☐	☐	☐	☐
Hallucinogens *(LSD, acid Psilocybin,Peyote, mescaline, PCP)*	☐	☐	☐		☐	☐	☐	☐	☐
Other, specify:	☐	☐	☐		☐	☐	☐	☐	☐

Notes:

Injection behaviors: *(complete if injected)*

	Never	Sometimes	Always	TFC
Shared needles	☐	☐	☐	
Cleaned works	☐	☐	☐	
Needle exchange	☐	☐	☐	

Shared with a known HIV+ partner ☐

NE is available in client's area. ☐

Needle/syringe sources: *(mark all that apply)*
☐ Needle exchange program ☐ Needle dealer/seller ☐ Close friend
☐ Secondary exchange ☐ Shooting gallery ☐ Sexual partner
☐ Pharmacy/drug store ☐ Diabetic ☐ Other source

	Never	Currently in treatment	Within last 2 yrs last result	Prior to last 2 yrs last result	TFC
Alcohol treatment history	☐	☐	☐	☐	
IDU treatment history	☐	☐	☐	☐	

OTHER RISK HISTORY

STDs/Hepatitis *(last 2 yrs' last result)*: *(mark all that apply)* ☐ Declined/Refused
☐ No STDs/Hepatitis ☐ Genital/anal warts (HPV)
☐ Syphilis *(syph, the pox, lues)* ☐ Genital herpes (HSV)
☐ Gonorrhea urethral *(GC, clap, drip)* ☐ Hepatitis A (HAV)
☐ Gonorrhea oral *(GC, clap, drip)* ☐ Hepatitis B (HBV)
☐ Gonorrhea anal/rectal *(GC, clap, drip)* ☐ Hepatitis C (HCV)
☐ Chlamydia ☐ Other,specify:
☐ Trichomoniasis *(trich)*

Viral STDs/Hepatitis *(lifetime history)*: *(mark all that apply)* ☐ Declined/Refused
☐ No lifetime viral STDs/Hepatitis ☐ Hepatitis A (HAV)
☐ Genital/anal warts (HPV) ☐ Hepatitis B (HBV)
☐ Genital herpes (HSV) ☐ Hepatitis C (HCV)

Hepatitis vaccination *(lifetime history)*: *(mark one each)*	Y	N	D
Completed vaccination series for hepatitis A (HAV)?	☐	☐	☐
Completed vaccination series for hepatitis B (HBV)?	☐	☐	☐

Other Risk Factor *(mark, if appropriate)*	Response: Y	N	D
Received money/other items or services for sex	☐	☐	☐
Received drugs for sex.	☐	☐	☐
Blood to blood contact (S & M, tattooing, piercing, cuts, or any behavior that allows mouth, vagina or anus to contact blood).	☐	☐	☐
Shared objects/fingers inserted in mouth, vagina or anus.	☐	☐	☐
Blood to blood exposure on the job.	☐	☐	☐

Response:	Y	N	D
Job exposure to blood known to be HIV+.	☐	☐	☐
Blood/blood product transfusion before 1985 (or in a country where blood is/was not tested for HIV antibodies).	☐	☐	☐
Child born to a HIV-infected woman.	☐	☐	☐
Other behavior:			
Notes:			

Client Test History: No. of prior HIV tests: _____ Last test date: _____ Last test result: ☐ P ☐ N ☐ I ☐ Did not return

Clinic Type: *(mark one)*
☐ HIV Test Site ☐ Mobile Van ☐ STD Clinic ☐ TB Clinic ☐ Detention Facility ☐ Primary Care/CHC ☐ Alternative Test Site ☐ Street Outreach
☐ Family Planning Clinic ☐ Alcohol/Drug Treatment Center ☐ Youth Drop-in Center ☐ Other Health Dept. ☐ Other, specify:

Client Test Election: *(mark one)* ☐ Tested confidentially ☐ Tested anonymously ☐ Declined testing/ not offered

Client's Reason for Testing: *(mark all that apply)*
☐ Reconfirming HIV+ result ☐ Reports AIDS-like symptoms ☐ Has current HIV+ partner(s)
☐ Had past HIV+ partner(s) ☐ TB diagnosis ☐ STD Related ☐ Hepatitis Diagnosis ☐ Pregnancy ☐ Starting a new relationship
☐ Partner request ☐ Rape/assault ☐ Exposure to blood ☐ Immigration ☐ Risky behavior Other: _____

TESTING SERVICES Scheduled Disclosure Date: _____ Actual Disclosure Date: _____ Disclosure Counselor ID: _____

Test For	Test Type					Test Result			Area of Diagnosis			
	Oral	Fingerstick	Veni-puncture	Urine	Other	Pos	Neg	Inc	Oral	Vaginal	Rectal	Urethral
HIV Rapid	☐	☐	☐			☐ prelim	☐	☐ invalid				
HIV Standard/Confirmatory	☐	☐	☐			☐	☐	☐				
STD-Syphilis			☐									
STD-Chlamydia				☐	☐	☐	☐	☐	☐	☐	☐	☐
STD-Gonorrhea				☐	☐	☐	☐	☐	☐	☐	☐	☐
STD-NGU				☐	☐	☐	☐	☐				☐
Hep ABC Panel ☐												
Hepatitis A			☐		☐	☐	☐	☐				
Hepatitis B			☐			☐	☐	☐				
Hepatitis C		☐	☐			☐	☐	☐				
Other	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Specify: _____												
Hepatitis B + (Additional Tests):												
Hep B - Anti-HBs						☐	☐	☐				
Hep B - Igm						☐	☐	☐				
Hepatitis C + (Additional Tests):												
Hep C - PCR						☐	☐	☐				
Hep C - Alt Value				Numeric Value:								

Syphilis Results:
☐ Negative
☐ Primary
☐ Secondary
☐ Early Latent ≤ 1 yr
☐ Late Latent > 1 yr
☐ Congenital
☐ Treated, Lab Negative
☐ Other: _____

FOLLOW-UP SERVICES

Follow-up Type	Follow-up Date	Follow-up Initial	Notes
☐ Disclosure			
☐ Post Disclosure			
☐ Referral			
☐ Partner Elicitation			
☐ Partner Notification			

RISK ASSESSMENT - RISK REDUCTION STEPS

R.A. Stage of Change: *(mark one)*
☐ Not thinking about it (Precontemplation) ☐ Thinking about it (Contemplation) ☐ Ready for action (Preparation) ☐ Action ☐ Maintenance

Goal Setting Name *(mark all that apply)*	Goal Setting at R.A.	Goal Result at Disclosure 1 2 3 4	Goal Setting at Disclosure	Goal Result at Post Disclosure 1 2 3 4	Goal Setting at Post Disclosure
Encourage condom (barrier) use for yourself and partner(s)	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Increase condom (and other barrier) use for yourself and partner(s)	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Decrease number of sexual partners	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Discuss sexual history with sex partner(s)	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Discuss safer sex options with sex partner(s)	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Discuss STD and HIV status with sex partner(s)	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Get tested for HIV and STDs more often	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Decrease frequency of alcohol and substance use with sex	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Use clean needles, works and other injection paraphernalia	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Limit number of sex partners at high risk settings: sex clubs, etc.	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Practice safer sex at high risk settings: sex clubs, circuit parties, etc.	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Limit high risk sexual activities at high risk settings: sex clubs, etc.	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Seek social/mental health support for substance abuse and/or sexual	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
Other, describe:	☐	☐ ☐ ☐ ☐	☐	☐ ☐ ☐ ☐	☐
1. No Goal Established 2. Client Made No Effort 3. Goal Attempted 4. Goal Achieved		☐ Test result is given	Schedule Post Disclosure Date:	Post Disclosure Date:	Post Disclosure Counselor ID:

Counselor: Review/Assess Introductory Issues
- ☐ Anonymity/confidentiality/non-names testing
- ☐ Risk assessment process and purpose of form
- ☐ What the HIV test measures
- ☐ Meaning/accuracy of test results (preliminary positive, positive, negative, inconclusive)
- ☐ Impact of HIV on the immune system

Counselor: Review/Assess Basic Issues
- ☐ Discuss safer sex guidelines
- ☐ Role-play with client to build needed skills
- ☐ Partner risks as they relate to client risk
- ☐ Risk reduction communication with partner
- ☐ Integration of birth control & risk reduction
- ☐ Pregnancy/maternal transmission (utero, birth, breastfeed)
- ☐ Demonstrate proper condom/barrier use
- ☐ Discuss obstacles to condom/barrier use
- ☐ Cultural/peer influences
- ☐ Domestic violence/sexual assault
- ☐ Voluntary PCRS/partner notification

Counselor: Review/Assess Testing Issues
- ☐ Window period/date of any follow-up test
- ☐ Process of testing
- ☐ Coping with waiting for test results
- ☐ Client's readiness to be tested
- ☐ Offer testing, if appropriate
- ☐ Encourage the client to return for results

Counselor: Review/Assess Drug and STD Issues
- ☐ Prevention/harm reduction/safer sex with IDUs
- ☐ Explore alcohol & drug treatment/recovery
- ☐ Behaviors affecting other STDs (e.g. rimming)
- ☐ Health effects of concurrent STD/HIV (e.g. pelvic inflammatory disease)
- ☐ Demonstrate proper needle cleaning
- ☐ Drugs with sex as co-factor for HIV risk
- ☐ STDs as a co-factor for HIV risk

REFERRALS

Client referrals: Referral date: _____

Record at risk assessment **(RA)**, disclosure **(D)** and post disclosure **(PD)**. Order by making **1** for your primary referral. Other referrals should be numbered **2** and **3**.

RA	D	PD	
___	___	___	(01) None
___	___	___	(02) Referral list only
___	___	___	(03) Other HIV testing

Risk/Harm Reduction

___	___	___	(04) Prevention case management (PCM)
___	___	___	(05) HIV education & prevention services
___	___	___	(06) Follow-up HIV counseling
___	___	___	(07) Prevention skill development
___	___	___	(08) Prevention support group
___	___	___	(09) Individual psychotherapy/counseling

Substance Use Services

___	___	___	(10) Alcohol/drug treatment
___	___	___	(11) Twelve step program
___	___	___	(12) Needle exchange program

HIV Positive Referrals

___	___	___	(13) Early intervention program (EIP)
___	___	___	(14) HIV case management
___	___	___	(15) HIV medical care/evaluation/treatment
___	___	___	(16) PCRS/partner notification

Other Referrals

___	___	___	(17) Post-exposure prophylaxis (PEP)
___	___	___	(18) Hepatitis testing/vaccination
___	___	___	(19) STD clinic
___	___	___	(20) Reproductive health services
___	___	___	(21) Other Non-HIV medical services
___	___	___	(22) Social services
___	___	___	(23) Other, specify: _____

PARTNER ELICITATION

[redacted]

PARTNER NOTIFICATION

[redacted]

For Clients Testing HIV-Positive Only:

Client's Medical Insurance Details

Financial Pre-Screening Date _____

Does the client have private Medical Insurance:	☐ Yes ☐ No
Does the client have HMO insurance?	☐ Yes ☐ No
Type of HMO	☐ Open System ☐ Close System ☐ Unknown
Does the client have Medi-Cal/Medicare?	☐ Yes ☐ No
Does the client have any kind of medical coverage	☐ Yes ☐ No
Client's insurance detail unavailable	☐ Yes ☐ No
Details of any other type of medical coverage/comments	☐ Yes ☐ No

Veteran Administration

Does the client have Veteran Administration benefits? ☐ Yes ☐ No

Referral

List the three (3) Medical/Outpatient referral sites:(Agency Name)

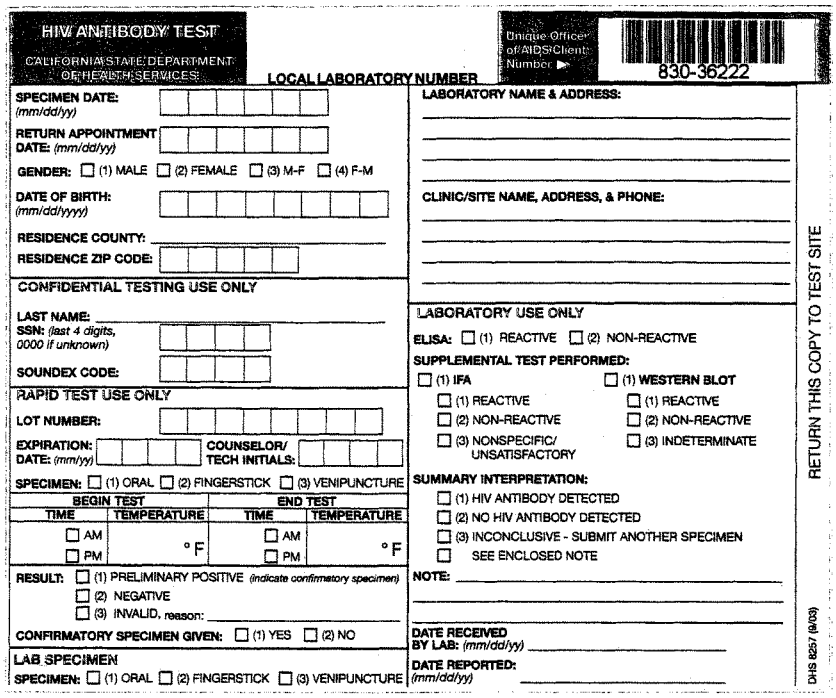
1. _____
2. _____
3. _____

HIV Non-name Reporting (Positive Clients Only):

Date HIV Case Report sent to HIV Epidemiology Office:

_____

Counselor Notes:



HIV ANTIBODY TEST

CALIFORNIA STATE DEPARTMENT OF HEALTH SERVICES

LOCAL LABORATORY NUMBER

Unique Office of AIDS Client Number ▶ 830-36222

SPECIMEN DATE: (mm/dd/yy)

RETURN APPOINTMENT DATE: (mm/dd/yy)

GENDER: ☐ (1) MALE ☐ (2) FEMALE ☐ (3) M-F ☐ (4) F-M

DATE OF BIRTH: (mm/dd/yyyy)

RESIDENCE COUNTY: _____

RESIDENCE ZIP CODE:

CONFIDENTIAL TESTING USE ONLY

LAST NAME: _____

SSN: (last 4 digits, 0000 if unknown)

SOUNDEX CODE:

RAPID TEST USE ONLY

LOT NUMBER:

EXPIRATION DATE: (mm/yy)

COUNSELOR/ TECH INITIALS:

SPECIMEN: ☐ (1) ORAL ☐ (2) FINGERSTICK ☐ (3) VENIPUNCTURE

BEGIN TEST		END TEST	
TIME	TEMPERATURE	TIME	TEMPERATURE
☐ AM ☐ PM	° F	☐ AM ☐ PM	° F

RESULT: ☐ (1) PRELIMINARY POSITIVE (indicate confirmatory specimen)
☐ (2) NEGATIVE
☐ (3) INVALID, reason: _____

CONFIRMATORY SPECIMEN GIVEN: ☐ (1) YES ☐ (2) NO

LAB SPECIMEN

SPECIMEN: ☐ (1) ORAL ☐ (2) FINGERSTICK ☐ (3) VENIPUNCTURE

283392 OF

LABORATORY NAME & ADDRESS:

CLINIC/SITE NAME, ADDRESS, & PHONE:

LABORATORY USE ONLY

ELISA: ☐ (1) REACTIVE ☐ (2) NON-REACTIVE

SUPPLEMENTAL TEST PERFORMED:

☐ (1) IFA
- ☐ (1) REACTIVE
- ☐ (2) NON-REACTIVE
- ☐ (3) NONSPECIFIC/ UNSATISFACTORY

☐ (1) WESTERN BLOT
- ☐ (1) REACTIVE
- ☐ (2) NON-REACTIVE
- ☐ (3) INDETERMINATE

SUMMARY INTERPRETATION:
☐ (1) HIV ANTIBODY DETECTED
☐ (2) NO HIV ANTIBODY DETECTED
☐ (3) INCONCLUSIVE - SUBMIT ANOTHER SPECIMEN
☐ SEE ENCLOSED NOTE

NOTE: _____

DATE RECEIVED BY LAB: (mm/dd/yy) _____

DATE REPORTED: (mm/dd/yy) _____

RETURN THIS COPY TO TEST SITE

DHS 8257 (9/03)

"Risk-Based Human Immunodeficiency Virus (HIV) Testing Fails to Detect the Majority of HIV-Infected Persons in Medical Care Settings"

Sexually Transmitted Diseases: Vol. 33; No. 5: P. 329-333 (05..06):: Timothy C. Jenkins, MD; Edward M. Gardner, MD; Mark W. Thrun, MD; David L. Cohn, MD; William J. Burman, MD

In order to assess opportunities for early HIV diagnosis in a comprehensive public health care system, the researchers undertook a retrospective review of patients newly diagnosed with HIV from September 2001 to December 2003.

Of 348 patients newly diagnosed with HIV, 120 (34 percent) had received medical care within the system during the three years prior to diagnosis. While 105 of the 120 patients had at least one previous interaction with the emergency room or urgent care center, only 12 HIV diagnoses (10 percent) were made in these two departments. Previously, 33 patients (28 percent) had presented with an STD or a clinical indicator of HIV.

In conclusion, the researchers reported that while one-third of patients newly diagnosed with HIV had clinical visits in the preceding three years, few of them presented with clinical conditions typically linked to HIV. "Targeted testing based on clinical presentations is not likely to result in substantially earlier HIV diagnosis," they wrote. "Routine screening in high prevalence settings could be more effective."

Journal of Acquired Immune Deficiency Syndromes
2002 January 1;29(1):76-85

Repeat HIV testing, risk behaviors, and HIV seroconversion among young men who have sex with men

Repeat HIV testing, risk behaviors, and HIV seroconversion among young men who have sex with men: a call to monitor and improve the practice of prevention.

MacKellar DA, Valleroy LA, Secura GM, Bartholow BN, McFarland W, Shehan D, Ford W, LaLota M, Celentano DD, Koblin BA, Torian LV, Perdue TE, Janssen RS; Young Men's Survey Study Group.

Division of HIV/AIDS Prevention-Surveillance and Epidemiology, National Center for HIV, Sexually Transmitted Diseases, and Tuberculosis Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia 30333, USA. dym4@cdc.gov

OBJECTIVES: We compared recent risk behaviors and HIV seroconversion among young men who have sex with men (MSM) who were first-time, infrequent, and repeat HIV testers.

METHODS: Male adolescents and young men aged 15 to 22 years were randomly sampled, interviewed, counseled, and tested for HIV at 194 gay-identified venues in seven U.S. cities from 1994 through 1998. Analyses were restricted to MSM who reported having never tested or last tested HIV-negative.

RESULTS: Of 3430 participants, 36% tested for the first time, 39% had tested infrequently (one or two times), and 26% had tested repeatedly (> or = three times). Compared with first-time testers, repeat testers were more likely to report recent risk behaviors and to acquire HIV (7% versus 4%). Over 75% of repeat testers who seroconverted acquired HIV within 1 year of their last test. Compared with repeat testers, first-time testers reported similar use of health care but delayed testing for nearly 2 additional years after initiating risk.

CONCLUSIONS: Many young MSM soon acquire HIV after repeated use of HIV counseling and testing services. Providers must strengthen practices to identify, counsel, and test young MSM and provide enhanced behavioral interventions for those with persistent risks.

Reuters Health
April 17, 2006

Wider testing spots hospital patients with HIV

NEW YORK (Reuters Health) - A new study supports the idea of expanding routine testing of hospitalized patients for HIV, beyond those who have traditional risk factors for HIV infection.

Despite a 1993 recommendation by the Centers for Disease Control and Prevention that clinical facilities with higher-than-average HIV disease rates offer testing routinely, Dr. Jeffrey L. Greenwald told Reuters Health that "essentially no one has followed this suggestion."

Greenwald, from Boston Medical Center, Massachusetts and his colleagues determined the proportion of inpatients who tested positive for HIV on routine testing who might not otherwise have been spotted had such testing not been offered.

Among a total of 243 subjects, 81 who tested positive for HIV and 81 who tested negative by the inpatient initiative were compared with 81 patients who tested positive for HIV in the ambulatory care setting.

Patients who tested HIV positive via inpatient testing had more advanced disease than those identified as HIV positive as outpatients, the investigators report in the Mayo Clinic Proceedings. At diagnosis, 64 HIV-positive inpatients (79 percent) had full-blown AIDS compared with 21 HIV-positive outpatients (26 percent).

Greenwald noted that "approximately half of the inpatients infected with HIV might not have been identified had testing been left to clinicians who test patients generally only when the clinical suspicion of HIV is significant."

In an accompanying editorial, Dr. Judith Feinberg of the University of Cincinnati, Ohio, notes that this study and the changes in federal policy regarding the expansion of testing "should spur physicians and other health care professionals to assume responsibility for identifying the quarter million individuals as yet undiagnosed" in the US.

SOURCE: Mayo Clinic Proceedings, April 2006.

AIDS Policy and Law
October 25, 2002
SECTION: HIV testing; Vol. 17, No. 20

Routine hospital tests could eliminate problem of undiagnosed HIV

Testing only high-risk or symptomatic patients for the HIV virus that causes AIDS is inadequate to identify the one-third of HIV-positive people in the United States who are unaware of their HIV infections, according to a report that detailed the results of a new pilot study.

The report, Identifying undiagnosed human immunodeficiency virus: The yield of routine, voluntary inpatient testing, states that about 300,000 people in the United States are unaware they are infected with HIV and that routine, voluntary testing could identify many of them. Researchers implemented the Think HIV program. They found that use of routine, voluntary HIV testing in all patients admitted to Boston Medical Center, which has a 1 percent prevalence of HIV infection among its patients, tripled the likelihood that patients would undergo HIV testing compared with patients admitted prior to the program.

Using this testing approach in 72 hospitals nationwide that have patient demographics similar to Boston Medical Center would identify an additional 31,800 HIV-infected patients per year, compared with current strategies that test only high-risk or symptomatic patients, according to the researchers who conducted the study.

The study was supported in part by the Agency for Healthcare Research and Quality.

Reuters Health
January 21, 2004

Low Adherence Foils ED Referral for HIV Testing

NEW YORK (Reuters Health) Jan 21 - **Just over 10% of patients referred by emergency department (ED) personnel for outpatient HIV testing actually showed up at an HIV clinic and, even then, not all were tested, researchers report in a study published in the January 1st issue of the Journal of Acquired Immune Deficiency Syndromes.**

As senior investigator Dr. Roger J. Lewis told Reuters Health, "this study demonstrates the need to improve the way we identify undiagnosed HIV infection in patients who seek care in our nation's emergency departments."

Dr. Lewis of Harborview UCLA Medical Center, Torrance, California and colleagues note that the rate of undiagnosed HIV infection is high in the socially disadvantaged, "the same patients who commonly seek care in public hospital EDs." Thus, "emergency physicians are in a unique position to target this group of individuals."

To investigate the utility of such an approach, the researchers had ED physicians refer patients who had any HIV risk factors or showed a diagnosis suggestive of HIV, for free testing and counseling at an HIV clinic.

However, poor patient compliance was a serious problem. **Of the 494 referred patients who met inclusion criteria, only 56 (11%) arrived at the HIV clinic and completed pretest counseling.** Of these, 51 (91%) were HIV negative, 4 (7%) were HIV positive and 1 (2%) refused the test.

The researchers, who are currently conducting a follow-up study to see whether a financial incentive may improve compliance, also suggest that "point-of-care testing using a rapid HIV test" may be another means of increasing detection.

New approaches are important, Dr. Lewis concluded, given that "a large proportion of at-risk patients delay testing or fail to get tested, even when they are referred for HIV testing, and thus miss an opportunity to learn their status, to protect others, and to potentially benefit from antiretroviral therapies."

J Acquir Immune Defic Syndr 2004;35:52-55.

Aidsmap news

Untested HIV-positive individuals more than twice as likely to engage in high-risk sex than those aware of their HIV-positive status

Edwin J. Bernard, Thursday, May 19, 2005

A meta-analysis of eleven studies has found that the prevalence of high-risk sexual behaviour is between 53-68% lower in HIV-positive individuals aware of their status than in HIV-positive individuals unaware of their status. The study, from the US Centers for Disease Control and Prevention (CDC) in Atlanta, was published electronically ahead of print in the *Journal of AIDS* at *JAIDS* online.

The US CDC estimates that of the 850,000 – 900,000 individuals currently living with HIV in the United States, 250,000 are unaware of their infection. However, the proportion of individuals unaware of their HIV infection varies substantially by risk group. **Earlier this year, the CDC published data which found that 77% of HIV-positive young gay urban men were unaware of their HIV status.**

Few data exists that compares the relative differences in high-risk sexual behaviour between those aware and unaware that they are HIV-positive. To this end, researchers from the CDC conducted a meta-analysis of published articles and conference abstracts that fulfilled the following criteria:

- data were from the United States.
- comparing a group of HIV-positive-aware individuals with an independent group of HIV-positive-unaware individuals.
- alternatively, measuring seroconverting individuals before and after receiving an HIV-positive diagnosis.
- measuring either unprotected insertive or receptive anal intercourse, unprotected vaginal intercourse and/or consistency of condom use during sexual intercourse.

Of 620 abstracts screened, eleven independent findings from eight studies conducted between 1988 and 2003 were included in the meta-analysis. These included four studies published in peer-reviewed journals and four multi-site data sets from the Multicenter AIDS Cohort Study (MACS), the HIV Epidemiology Research Study (HERS), the Supplement to HIV/AIDS Surveillance (SHAS phase 1, 1995-2000) and SHAS phase 2, 2000-2003. Six of the findings compared the high-risk sexual behaviour of individuals who were aware that they were HIV-positive with HIV-positive-unaware individuals (between-group comparisons) and five compared seroconverting individuals before and after being notified of their HIV-positive status (within-subject comparisons).

McCusker et al, *Am J Public Health*
This study from 1988 was a between-group comparison of HIV-positive gay men recruited at a Boston health clinic who reported engaging in unprotected anal intercourse (UAI) before getting HIV test results. The CDC calculated a 59% reduction in prevalence of high-risk sexual behaviour between HIV-positive-aware individuals and HIV-positive-unaware individuals.

Valleroy et al, *JAMA*
This between-group study, from 2000, of HIV-positive gay and bisexual men recruited at seven urban sites found that 37% of HIV-positive-unaware men engaged in UAI with any partner in the previous six months, compared with 13% of the HIV-positive-aware men. This was calculated as a 65% reduction in prevalence of high-risk sexual behaviour between groups.

SHAS, phase 1
The CDC calculated that the between-group reduction in prevalence of high-risk sexual behaviour with any partner in this study of HIV-positive men and women surveyed in twelve cities or states between 1995-2000 was 63% for men and 59% for women.

SHAS, phase 2
The CDC calculated that the between-group reduction in prevalence of high-risk sexual behaviour with at-risk partners in this study of HIV-positive men and women surveyed in 19 cities or states between 2000-2003 was 59% for men and 56% for women.

Cleary et al, *Am J Public Health*
This study from 1991 was a within-subject comparison of 153 HIV-positive male and 43 HIV-positive female blood donors from New York between 1986 and 1988. It reported on the difference in sexual behaviour (unprotected anal or vaginal intercourse, or unprotected oral sex) in the week before and up to two weeks after diagnosis. The CDC calculated a 41% reduction in these sexual behaviours for men, and a 34% reduction for women, after an HIV-positive diagnosis.

HERS
Fourteen women (79% injecting drug users) from multiple urban sites provided a within-subject comparison of unprotected anal or vaginal intercourse with any "casual" sex partner in the twelve months prior to, and 18 months after an HIV-positive diagnosis. The CDC calculated a 52% reduction in high-risk sexual behaviour after an HIV-positive diagnosis.

MACS
This within-subject study of 90 gay and bisexual men recruited at urban locations who seroconverted between 1988 and 1999 compared unprotected anal intercourse with any sex partner in the twelve months prior to, and 18 months after an HIV-positive diagnosis. The CDC calculated a 25% reduction in high-risk sexual behaviour after an HIV-positive diagnosis.

Colfax et al, *AIDS*
Forty-three gay and bisexual men from urban locations provided a within-subject comparison of unprotected insertive anal intercourse with a partner reported to be HIV-negative or of unknown HIV status in the six months prior to, and six to twelve months after an HIV-positive diagnosis. The CDC calculated a 59% reduction in high-risk sexual behaviour after an HIV-positive diagnosis.

The CDC researchers then calculated the effect size (i.e. the likelihood that knowledge of HIV-status resulted in a reduced prevalence of high-risk sex) of these studies. They found that, using an unadjusted model, the combined effect size for all eleven findings was an average of 53% (95% CI: 45-60%) lower in HIV-positive-aware individuals relative to HIV-positive-unaware individuals.

After adjusting the data to focus on unprotected anal or vaginal intercourse with partners who were not already HIV-positive, the researchers calculated

that being aware of one's HIV-positive status resulted in a 68% (95% CI: 59-76%) reduction in high-risk sex. The reductions were larger in between-group comparisons than in within-subject comparisons ($p < 0.01$), with no significant differences found between men and women ($p > 0.10$).

The researchers point out several limitations with the studies examined in the meta-analysis, in particular the use of self-reported sexual behaviour, which tends to lead to under-reporting of high-risk sex. The studies could also not ascertain HIV transmission risk, which is subject to many variables, including stage of HIV infection, viral load, and other concurrent sexually transmitted infections.

They argue, however, that their findings "reinforce the need for a multidimensional approach to HIV prevention". This would include scaling-up resources and efforts "to make HIV testing opportunities more accessible and to reduce barriers to testing so that infected persons learn their status".

They conclude by suggesting that HIV counselling and testing is not enough to control the HIV epidemic, and that the continued high-risk sexual behaviour of people aware of their HIV-status can also be modified through behavioural interventions, although "the challenge is to find settings and approaches for delivering prevention programs to this population over time". They suggest a multi-factorial approach that includes counselling in HIV clinics, peer intervention and "assisting HIV-positive persons to establish social networks that encourage risk reduction and provide social support for seeking medical care and adhering to treatment regimens".

Reference

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http://bmj.bmjjournals.com/cgi/content/full/330/7490/492
BMJ 2005;330:492-493 (5 March), doi:10.1136/bmj.330.7490.492

HIV testing

Should no longer be accorded any special status

Before highly active antiretroviral therapy (HAART) was introduced, the advantages to infected individuals of knowing their HIV status were minimal, and counselling before HIV testing was the recommended practice.[1] This usually limited testing, by relying on people who were obviously at risk presenting themselves for testing. Such groups included injecting drug users and men who have sex with men and their sexual contacts. Targeting of these groups will become an increasingly less useful concept as HIV continues to spread into the population that is conventionally not at risk. Do we need to reconsider if routine voluntary counselling and testing is appropriate today?

Since 1991 heterosexual transmission of HIV has been the most common mode of transmission in the United Kingdom.[2] Currently, nearly half of those infected heterosexually and a quarter of infected men who have sex with men in the United Kingdom are undiagnosed.[3] A quarter of newly diagnosed patients in the United Kingdom in 2002 were diagnosed late with serious immunosuppression.[3] Unless further initiatives are undertaken the epidemic will worsen. Possible initiatives would be to lower thresholds for HIV testing by reducing the emphasis on pre-test counselling.

Reasons for low HIV testing rates and thus low detection rates include concerns about confidentiality, legal and insurance issues, self perceptions of low risk in those who would test positive, denial, dislike of counselling, and wishing to avoid anxiety when waiting for results.[4,5] Fear and denial are the commonest obstacles to HIV testing among those acknowledging that they have been at risk.[6]

Additionally doctors' awareness of the effectiveness of early interventions is low and they may not encourage HIV testing.[7,8] The most common reason,

however, is lack of time for pre-test counselling, even in genitourinary medicine clinics.[9] Average times for counselling are not less than 21 minutes with 18% of people requiring two sessions.[1]

Low detection rates imply longer duration of infections, which imply increased risk of HIV transmission. In an unpublished study, 70 randomly selected, HIV positive patients attending our centres were estimated to have been infected for a mean of 8.5 years. In that study, for only 56% had doctors broached HIV testing, only 6% of patients had ever declined HIV testing, and 46% of those who were HIV positive reported that their explicit consent to testing should not have been needed. Such results need to be replicated, but implications are clear.

Lowering the threshold for HIV testing will lead to early diagnosis and treatment of infected individuals, which may prevent the development of AIDS and the transmission of infection.[10,11]

What is the role of voluntary counselling and testing? Voluntary counselling and testing has been accepted practice for more than 10 years. Uptake of voluntary counselling and testing, however, has been poor, even in those with high risk sexual activities.[2] Sizeable proportions of infected people never attend genitourinary medicine clinics for voluntary counselling and testing even if referred. In addition, it seems that pre-test counselling is, on balance, not dramatically effective in reducing high risk sexual activity.[12]

Many HIV infected individuals receive medical attention before they are diagnosed and opportunities for testing may have been discouraged by the "need" to perform or organise voluntary counselling and testing. Such patients would include, for example, those with persisting lymphopenia, neutropenia, or thrombocytopenia. A routine approach to testing would almost certainly increase the number of early HIV diagnoses, which would then allow concentration on subsequent informed counselling and education of patients and their partners and possible reduction in spread of infection.

Highly active antiretroviral therapy has rendered HIV similar to other serious diseases. We believe that HIV testing should be widely accepted, without conventional voluntary counselling and testing, as patients at risk of cancer do not receive voluntary counselling and testing before chest x rays, or patients with chest infections do not routinely receive voluntary counselling and testing before stains for acid fast bacilli on sputum are requested.

The current combination of reluctance of busy doctors to initiate pre-test counselling and denial by patients has resulted in late diagnosis and ongoing spread of infection. We propose that if a patient freely consents to be investigated, a doctor can initiate tests aimed at excluding serious diseases without an in depth discussion of all possible results, provided that the test result, positive or negative, should benefit the patient.

Routine voluntary counselling and testing was appropriate to the 1980s. Times have changed. The benefits of early diagnosis of HIV are multiple. HIV testing should now not be accorded any special status. Doctors should now undertake the test by using the same approach as used in any other test with serious implications.

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Competing interests: None declared.

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New York Times
May 15, 2006

EDITORIAL

New Guidelines for AIDS Testing

Despite widely available testing, about a quarter of the Americans infected with H.I.V. don't know it. Those who are unaware of their infections can spread then unknowingly. They also miss out on powerful drug therapies that have been shown to extend lives, while protecting infected people from the diseases to which H.I.V. makes them prone.

Rapid AIDS tests — which have cut the waiting time for results to 20 minutes from as much as two weeks — have greatly helped the outreach effort. But the Centers for Disease Control and Prevention will take another important step forward this summer when it offers new guidelines for AIDS testing. The proposed recommendations are a sea change in the testing regimen, suggesting that doctors offer the tests not just to people at risk, but as part of routine medical care for all patients ages 13 to 64.

The C.D.C. will also address two current obstacles to treatment. First, the agency will recommend that health care providers shorten and simplify a counseling session that often takes place before the person is tested. In addition, the new guidelines will suggest that patients be allowed to give oral consent to testing — rather than being required to sign a separate permission form.

AIDS activists have long insisted on the separate form, worried that patients might be tricked into taking a test that they might ordinarily shun, and perhaps expose infected people to discrimination. Such worries have proved unfounded; health authorities have demonstrated that they can be trusted to keep the information confidential. Moreover, it makes perfectly good sense to treat AIDS like any other infectious or sexually transmitted disease, especially given the wide availability of lifesaving treatment today.

The New York Times
February 2, 2006 Thursday
Late Edition - Final
SECTION: Section B; Column 4; Metropolitan Desk; Pg. 1

Overhaul Urged for Laws On AIDS Tests and Data

By MARC SANTORA

New York City's health commissioner, Dr. Thomas R. Frieden, called yesterday for changing state laws so that health officials could more aggressively test people for H.I.V. and AIDS and use the medical information the city already collects to help treat those infected.

Currently, the city and the state collect detailed data about specific patients with H.I.V./AIDS, with their names attached, but health officials are prevented by law from using that information to contact those patients or their doctors about their treatment.

In addition to wanting to change those laws, Dr. Frieden also wants to make testing for the virus a routine part of medical care, simplifying the process by which a patient consents to be tested.

"We know people are dying," Dr. Frieden said yesterday as he outlined his proposals publicly for the first time. "And we are prohibited by law from lifting a finger to try and help."

The collection of state laws governing the public health response to H.I.V./AIDS was created nearly two decades ago, and it has been fiercely defended by both lawmakers and patient advocates ever since. From the beginning, AIDS was treated differently from any other infectious disease, so Dr. Frieden could face stiff political resistance. He stressed that he is in no way proposing mandatory testing or treatment.

The central law that Dr. Frieden, with the support of the Bloomberg administration, is taking aim at was put in place in 1988, when contracting H.I.V. was the equivalent of a death sentence because

there was no effective treatment, much less a cure. With the disease primarily affecting gay men, those who found themselves identified as sick with the disease were often subjected to discrimination and hostility.

The state laws, particularly those governing privacy concerns, were an attempt to encourage people to be tested and treated while offering them some protection. Since then, an extensive advocacy network has grown both to help patients and to lobby public officials to protect the information about patients with the virus.

With the introduction of effective drug treatments in the late 1990's, the death rates from AIDS have plummeted, and great strides have been made in reducing mother-to-child transmission of H.I.V. as well as in cutting the rate of transmission among intravenous drug users.

For the past decade, however, new infections continue to occur at troubling rates, and the population affected has changed drastically, with blacks and Hispanics accounting for 80 percent of new diagnoses and deaths. Transmission through heterosexual sex, particularly among black women, has also risen significantly.

Today, black men with the disease are six times as likely to die of the disease as white men, and black women are nine times as likely to die as white women.

Dr. Frieden believes that this disparity reflects the way efforts to test for the disease and treat it have not evolved to keep pace with the changing nature of the epidemic. His proposals, he contends, would help those in a population that does not get tested early enough, who are often sick by the time they know their status, and who are often stranded without the good medical care available to the more prosperous.

In his State of the City address last week, Mayor Michael R. Bloomberg signaled his strong support for an aggressive new approach, saying, "Over the next three years, our goal is to cut the number of H.I.V.-related deaths by more than 40 percent."

Dr. Frieden believes that a change in state law is needed to achieve

that goal, although he readily acknowledges that getting changes made in Albany will be an uphill fight. City health officials have been working for months to win support for the changes, and some community health leaders have publicly endorsed the approach. But when Dr. Frieden presented his proposal publicly at the New York State AIDS Advisory Council meeting yesterday, he was met with skepticism.

The primary concern was that changing state laws would loosen New York's stringent privacy protections.

State Senator Thomas K. Duane, a Manhattan Democrat, said that the disease still carried a stigma and that it was unwise to move too quickly. "It is our responsibility to be incredibly cautious for those who do not have much of a voice," Mr. Duane said. He later added, "I don't, at this moment, agree that we need to open Pandora's box."

Dr. Frieden, saying that privacy would continue to be of paramount importance, cited statistics on delays in diagnosis that he said put lives at risk. For example, in 2004 there were 1,038 patients who first learned they had H.I.V. when they were already sick with AIDS. "That's a damning indictment of our system," he said.

Dr. Frieden has pushed for more aggressive collection of data in the past, most publicly after he announced the detection of what he called a rare and possibly virulent strain of the virus detected in a New York man in February last year. The proposals he outlined yesterday go much further.

New York has the highest H.I.V./AIDS rates in the country, with more infected people than Los Angeles, Washington, San Francisco and Miami combined. Dr. Frieden noted that any changes the city and the state make are sure to be closely watched.

Prof. Charles Gilks, an official at the World Health Organization who directs one of its H.I.V./AIDS programs, sent Dr. Frieden a note of support. "Many countries take their lead from the U.S. or Europe," he wrote in an e-mail message.

When questioned about his plan, Dr. Frieden suggested that he

wanted to do away with the written consent forms now required before any test is given by a health care provider, while still requiring spoken consent. He also said he supported doing away with the requirement that physicians detail the reasons a patient may not want to be tested for H.I.V.

The city and the state collect detailed patient data for a variety of infectious diseases that laboratories across New York are mandated to report, including information about H.I.V./AIDS. Dr. Frieden contends that health officials should be able to use that information to consult directly with patients and their doctors. He said that information would not be given to the wider health care community.

In an interview, he said that as one example, if the city had information that a patient had an extremely high viral load and a low T-cell count indicating that the person was likely to die within months unless action was taken, health workers would reach out to the treating physician.

Terri Smith, the public policy director for Housing Works, a patient advocacy group, said she was concerned about an unknown health department employee contacting a patient's doctor.

Dr. Frieden said that because everything remained voluntary, he believed that both physicians and patients would eventually welcome the changes.

San Francisco Chronicle
May 18, 2006
Page B-3
http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2006/05/18/BAGHTITPRQ1.DTL&type=health

SAN FRANCISCO

City health agencies move to streamline HIV testing San Francisco drops counseling requirement

By Erin Allday, Chronicle Staff Writer

San Francisco's public medical clinics and hospitals will no longer require written consent and counseling sessions before HIV tests, and public health officials say they hope the easier, less time-consuming process will prompt more people to get tested.

The shift in policy, which took effect Tuesday, follows a similar proposal from the Centers for Disease Control in March, as the health care industry grapples with estimates that more than 20 percent of those infected with HIV don't know it -- and continue to spread the disease.

San Francisco is the first city in the country to adopt the new policy, under which people will have to give verbal, not written, permission for testing. Pretesting counseling will still be offered to those who want it, but it will no longer be mandatory, said Dr. Jeffrey Klausner, director of STD Prevention and Control for the San Francisco Department of Public Health.

Last year, 20,000 people were tested for HIV in San Francisco, and 440 of them tested positive, Klausner said.

"When I reviewed testing records earlier this year I was shocked to see a substantial proportion of people were not testing for bureaucratic reasons," Klausner said. "In medical practice, people get screened and tested for serious conditions all the time. People get mammograms, they get biopsies, these can be done without these bureaucratic hurdles. The several layers of paperwork, the required counseling for HIV testing, they were actually a barrier."

For decades, medical facilities have required written consent and counseling for HIV testing because AIDS was such a deadly disease and there was a "substantial stigma" associated with it, Klausner said.

But with new treatments available and heightened public awareness of AIDS, the strict pretesting process had become outdated and overly formal, he said. Public health officials worried that the extra precautions -- along with the wait time that

required 20-minute counseling sessions -- were discouraging people from getting tested.

Klausner said San Francisco's public health department began dismantling its pretesting counseling program last summer, when the city removed funding for counseling positions at public clinics and hospitals. Since then, the medical providers actually conducting the tests have been providing counseling.

Several AIDS organizations have expressed concerns about the CDC proposal, which is still being discussed, suggesting that policies like San Francisco's could threaten patient privacy, although Klausner said that HIV testing will meet the same strict patient confidentiality rules.

Steven Tierney, deputy executive director of the San Francisco AIDS Foundation, said he supports programs that will encourage more people to get tested, but he doesn't want the testing process to be "over-simplified" to the point that people aren't making informed decisions based on conversations with a counselor or their medical provider.

"Anything that makes it easier to get tested is a good thing, but we believe folks have a right to full, informed consent," Tierney said.

E-mail Erin Allday at eallday@sfchronicle.com.

Reuters
March 28, 2006

Clinton calls for rethink of AIDS testing policy

By Patricia Reaney

LONDON, March 28 (Reuters) - Former U.S. President Bill Clinton called on Tuesday for mandatory testing for HIV/AIDS in countries with high infection rates and the means to provide lifesaving drugs. When the AIDS epidemic began two decades ago mandatory testing was frowned on because of the stigma attached to the deadly illness and the lack of treatment for those infected. But Clinton said countries where there was no discrimination against people with the illness and where anti-AIDS drugs were available should now consider universal testing.

"I think there needs to be a total rethinking of this testing position in the AIDS community and a real push for this," Clinton told journalists during a briefing in London.

More than 40 million people worldwide are estimated to be living with HIV/AIDS but many do not know they are infected.

"Now we can save people's lives and we can reduce the stigma. There is no way we are going to reduce the spread of this epidemic without more testing because 90 percent of the people who are HIV positive don't know it," he added.

LESOTHO TEST CASE

Clinton, whose foundation has been working to bring quality medical care and cheaper drugs to sufferers in poor countries, said this year Lesotho would become the first country to do universal testing.

He said he regarded it as a test case to see whether rapid tests, costing 49-65 cents each, and drugs can reduce the 27 percent infection rate in the southern African country. A budget of $100 million could pay for 200 million tests.

"The whole idea is to treat this as a public health problem, not as some source of shame or disgrace and to keep as many people alive as possible," he explained.

The first aim is to stop infections and the second to save the lives of those who are infected.

"I would be for whatever accomplishes those objectives," Clinton said.

He added the question was not whether a country was rich or poor but its infection rate. When the level of infection reached a critical point it imperilled the public health structure and social stability, making it more difficult to bring rates down.

Since leaving the White House Clinton has devoted much of his attention to getting anti-AIDS drugs to poor countries at the cheapest possible prices through the Clinton Foundation HIV/AIDS Initiative (CHAI).

It is working with 22 countries in Africa, the Caribbean and Asia to provide anti-AIDS drugs to more than a quarter of a million patients through special drug deals.

"I made up my mind that I would not spend the rest of my life wishing I was still president," he said when asked about his his post-presidency projects. "Once you let it go, you have got to let it go."

United States Senate

WASHINGTON, D.C. 20510

February 15, 2006

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 615-F
Washington, D.C. 20201

Dear Secretary Leavitt:

We are writing to express our concern regarding Food and Drug Administration's (FDA) *Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications* (Docket Number 2001D-0044).

In recent years, the Department of Health and Human Services (HHS), under the leadership of then Deputy Secretary Claude Allen, was instrumental in ensuring the expeditious FDA approval of OraQuick, the first, second-generation rapid test. HHS once again provided leadership in ensuring that rapid tests would be waived under CLIA, in a manner that best meets the public health need. These new *Recommendations* undermine these victories by virtually ensuring that any future HIV, STD, or hepatitis test will not qualify for a CLIA waiver. A CLIA waiver is critical in that it will allow these types of tests to be used at the point-of-care where individuals at risk for these diseases are reached.

While we appreciate that the document was released for comment only and changes remain possible, it is distressing that several provisions have remained in the regulations.

Troubling provisions include:

- The recommendation that no test for a reportable disease be eligible for a CLIA wavier will eliminate HIV and other STD tests from consideration.
- The recommendation for inclusion of a sample collection device and shipping materials for confirmation testing is highly burdensome and has been shown to be unnecessary.
- Provisions for clinical studies allowing only the use of up to 10% of archived samples would make the cost of seeking a waiver prohibitive for many diseases including HIV.

Through deployment of the OraQuick Advance and Uni-Gold rapid tests, many individuals have learned their HIV status and been linked to care, support, and prevention services. These tests have been successfully implemented by health department AIDS programs in conjunction with their public health laboratory counterparts. Programs have demonstrated these tests can be used at the point-of-care while assuring the quality of testing and with individuals receiving accurate results.

These tests present no risk to the general public through their use. The proposed recommendations do not take the current experience and knowledge regarding these tests into consideration.

The use of HIV rapid tests at the point-of-care is a major tool required for the success of the Centers for Disease Control and Prevention's (CDC) *Advancing HIV Prevention* initiative. In his principles for re-authorization of the Ryan White CARE Act, the President has shown his support for this initiative, recognizing its importance in ensuring individuals know their status and have the opportunity to stop transmission of diseases that have such a large impact on an individual's health and well being.

We recognize the need for clear, objective standards for CLIA waiver applications to allow companies to make informed decisions about whether to seek waived status for their devices. However, it is highly concerning that the FDA would even consider recommendations that would create barriers to tests being available to meet a clear public health need. The public depends upon HHS and its agencies to protect their health. This includes ensuring that individuals have all the opportunities available to them to learn of any disease that may impact their health along with opportunities for treatment and support. To issue these recommendations would compromise the public health and be a significant set back to achieving the Administration's stated priority of increasing earlier knowledge of infection status.

We urge the FDA to reconsider these recommendations and the process that developed them. FDA should seek guidance and input from its federal partners such as CDC's Division of HIV/AIDS Prevention and the Department leadership before proceeding. Also, it would best serve the FDA to seek information from health department AIDS programs and the community at large to better understand the need for this type of testing and their current experience with CLIA waived HIV rapid testing.

Thank you for your attention to this matter. We look forward to working with you to reach the Administration's goals of early diagnosis and access to treatment.

Sincerely,

Tom A. Coburn, M.D.
U.S. Senator

Barack Obama
U.S. Senator

Arlen Specter
U.S. Senator

Richard Burr
U.S. Senator

"Support Among Persons Infected with HIV for Routine Health Department Contact for HIV Partner Notification"

Journal of Acquired Immune Deficiency Syndromes (02.01.03) Vol. 32; No. 2: P. 196-202:: Matthew R. Golden; Sharon G. Hopkins; Martina Morris; King K. Holmes; H. Hunter Handsfield

A central goal of CDC's recently announced Serostatus Approach to Fighting HIV (SAFE) is to increase the proportion of Americans with HIV who are aware that they are infected. One way to reach that goal may be through enhanced partner notification (PN). However, PN for HIV is controversial. Many persons diagnosed with HIV do not receive PN services from public health agencies, and existing data suggest that a majority of private providers do little more than advise their patients to notify their sex or needle-sharing partners themselves.

Efforts to link named HIV reporting to PN have been met with resistance throughout the United States. In spite of this opposition, there are few data on what people with HIV, particularly men who have sex with men (MSM), actually think about PN and how the process could be more acceptable and effective. To address such issues, the authors surveyed a random sample of persons with prevalent HIV diagnoses seen in the Harborview Medical Center (HMC) HIV/AIDS Clinic located within the public hospital of King County, Wash. Persons with newly diagnosed HIV reported to Public Health-Seattle and King County (PHSKC), the health department serving Seattle and King County, were also surveyed. A total of 95 persons, of whom 76 (80 percent) were MSM, completed an anonymous self-administered questionnaire and were included in the analysis.

Study participants reported a mean of 3.2 anal or vaginal sex partners (median=1.0, range: 0-60) in the six months prior to completing the survey. Forty participants (42 percent) reported having unprotected anal or vaginal sex in the preceding six months.

Eighty-four percent of participants believed the health

department should routinely offer everyone diagnosed with HIV help in notifying their partners. Age, race, MSM, income level, diagnosis outside of a public health testing site, anonymous HIV testing, and receiving HIV care at the HMC HIV clinic were not significantly associated with support or opposition to offering PN assistance.

Seventy-nine percent indicated they would be very likely or somewhat likely to provide information to a doctor, case worker, or health department employee for purposes of PN; and 20 percent indicated they wanted help in notifying a recent sex partner.

Seventy-eight percent of study participants believed the health department should contact all HIV-infected persons after diagnosis to help them access medical care and social services, and 68 percent wanted the health department to contact them about the availability of medical or social services. Persons diagnosed in settings other than public health clinics were less likely to have spoken with a social worker or case worker since their HIV diagnosis than those diagnosed in public health clinics (65 percent vs. 93 percent). Persons diagnosed outside of the public health system were more likely to report wanting to speak to a social worker about the availability of medical and social services (49 percent vs. 29 percent).

The authors' central finding is that most people with HIV, including MSM, support the universal provision of confidential and voluntary public health PN services and that restricting PN programs to public health deprives some patients of desired services.

In consideration of these findings, clinical providers, community-based organizations, and health departments should reassess whether narrowly focusing PN services on persons at public health sites truly reflects patient preferences. **"Efforts to improve PN should concentrate on greater integration of the process into the provision of the medical and social services patients already receive," the authors concluded.**

Reuters Health
December 4, 2003

Partner testing key weapon in AIDS battle

By Paul Simao

ATLANTA (Reuters) - **Comprehensive efforts to test the partners of those newly diagnosed with the HIV infection could uncover thousands of infections and help contain the spread of the disease, according to a new study released on Thursday by the U.S. Centers for Disease Control and Prevention.**

About one quarter of the estimated 950,000 Americans living with HIV do not know they are infected. Diagnosing and treating this group before they spread the virus has become a cornerstone of the U.S. government's AIDS strategy.

A recent analysis of public health data from North Carolina found that more than 20 percent of those who had sex or shared needles with people diagnosed with HIV in 2001 learned they had the virus when voluntarily tested.

In comparison, less than 1 percent of HIV tests at public health facilities in the state in 2001 were positive.

Dr. Sam Dooley, associate director for science in the CDC's division of HIV/AIDS prevention and one of the study's authors, praised North Carolina for investing resources and preparing the public for targeted HIV partner testing and counseling.

"If it were done to this extent and this degree of success across the board, we would see a significant number of those folks who don't know they're infected learning that they are," Dooley said.

The North Carolina study comes amid signs of a resurgence of HIV in the United States. In the past year, health officials have reported a rise in infections among intravenous drug users as well as syphilis outbreaks among gay and bisexual men.

Studies have shown that sexually transmitted diseases increase the likelihood of HIV infection. Up to 70 percent of gay and bisexual men infected in recent syphilis outbreaks have tested positive for HIV.

The disturbing trends prompted the CDC earlier this year to recommend that routine HIV testing be expanded to include pregnant women, intravenous drug users and anyone who engaged in unsafe sex.

Routine screening had previously been recommended only for those seen at acute care hospitals with a high incidence of HIV cases and for patients in clinics that specialized in treating sexually transmitted diseases.

About 16,000 Americans die each year from AIDS and another 40,000 become infected with HIV.

SOURCE: Morbidity and Mortality Weekly Report, December 5, 2003.

The Boston Herald
Wednesday, March 8, 2006
NEWS; Pg. 17

Healey: Test suspects in sex-crimes for STDs

By MAGGIE MULVIHILL

Victims of sex crimes in Massachusetts have the right to know if their attacker has a sexually transmitted disease, Lt. Gov. Kerry Healey told a legislative committee yesterday.

Healey was advocating for a bill proposed by Gov. Mitt Romney in January that would require accused sex criminals to be tested for STDs, including HIV infection.

Massachusetts is one of only five states that do not mandate STD testing of a defendant charged with a sex crime.

``This legislation will provide crucial information and peace of mind to victims of sexual assault," Healey told the Joint Committee on the Judiciary.

Healey's push for the legislation accelerated in January when a Framingham man, who is allegedly HIV-positive, was charged with rape. Evandro F. Doirada, 28, pleaded not guilty in Brockton Superior Court on Jan. 25 to allegations he kidnapped the victim and her two-year-old son at knifepoint from the Framingham Wal-Mart on Dec. 17 and raped her for two days at the Plymouth Sands Hotel.

If the alleged attacker tests positive, victims can start the post-exposure prophylaxis medication cycles they need. If they test negative, victims can stop the medications which can produce painful side effects, Healey said.

``If this can provide any modicum of relief after the rape then barriers should be removed so victims . . . can make informed decisions about their life and their health care" said Toni Troop, a spokeswoman for the victims-rights group Jane Doe Inc.

But some civil libertarians and AIDS activists oppose the bill, claiming by

the time an STD test is done it is too late for the victim to start preventative drugs.

``In most medical settings it can take two to three weeks and that simply is not going to help a survivor," said Ben Klein, AIDS Law Project Director for Massachusetts Gay & Lesbian Advocates & Defenders.

``Generally, a survivor needs to make a decision about whether to undergo preventative treatment with HIV medication within 72 hours at the outside."

The Boston Herald
Thursday, March 9, 2006

Testing bill puts victims first

By Boston Herald editorial staff

Once again, Massachusetts finds itself in the minority when it comes to important public safety legislation. Turns out the Bay State is one of only five states in the nation that don't require rape suspects to submit to testing for HIV and other sexually transmitted diseases.

Lawmakers can change that, though, by passing a bill filed by Gov. Mitt Romney earlier this year that draws a critical distinction between the rights of the accuser and the rights of the accused. Inspired by the horrifying case of a woman who was kidnapped and held hostage in a Plymouth motel and raped repeatedly in front of her 2-year-old son, the bill would allow victims to request that their alleged attackers be tested for HIV and other sexually transmitted diseases - then get the results.

Civil libertarians and AIDS activists argue such a law violates the privacy of the accused. But just once, it would be nice if lawmakers saw the wisdom in passing bills that protect victims before tragedy strikes.

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United States Senate

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COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

CHAIRMAN
SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, AND HOMELAND SECURITY

COMMITTEE ON THE JUDICIARY

CHAIRMAN
SUBCOMMITTEE ON THE ARCHITECTURE AND APPELLATE RESTRUCTURING

COMMITTEE ON INDIAN AFFAIRS

March 14, 2006

Honorable Kerry Healey
Lieutenant Governor
The Commonwealth of Massachusetts
State House Room 360
Boston, MA 02133

Dear Lieutenant Governor Kerry Healey,

As a practicing physician and a U.S. Senator, I applaud you for your leadership on protecting victims of rape and sexual assault from sexually transmitted diseases (STDs). I was recently made aware of your efforts seeking to pass a state law to allow testing of alleged rapists for STDs. I commend your efforts and wanted to bring to your attention a new federal law that may provide a financial incentive for the members of the Massachusetts legislature to approve your proposal.

Congress recently approved and the President signed into law a bill reauthorizing the Violence Against Women Act (Public Law:109-162). The Act was amended to reduce the amount of money available in Section 102 by 5 percent for states which fail to enact a law that would allow a victim of sexual assault to request that the alleged perpetrator be tested for HIV, the virus that causes AIDS.

The legislation you are suggesting would bring Massachusetts into compliance with this new federal law and ensure that your state remains eligible for the full amount of grants available under Section 102. States have until the completion of the next session of their State Legislature or two years (whichever is longer) to have a law that ensures testing of alleged rapists for HIV. Those states that do not comply with this provision, will be ineligible for 5 percent of the funds they would otherwise be eligible to receive, and the extra funds will be divided by states that are in compliance.

Section 102 provides funding to states and localities to develop and strengthen programs and policies that encourage police officers to arrest abusers who commit acts of violence or violate protection orders. Many local law enforcement departments use these grants to hire additional officers to focus on obtaining arrest warrants for abusers who flee the scene of the crime or violate protection orders. Without these funds many departments, at least in my state of Oklahoma, would not have the manpower to track, arrest, and charge abusers. The allowed purposes of this section were expanded to encourage victim service programs to collaborate with law enforcement to assist pro-arrest and protection order enforcement policies. In addition, this section authorizes family justice centers and extends pro-arrest policies to sexual assault cases.

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At the request of law enforcement and various states, Congress increased the amount authorized under Section 102 from $65 million for fiscal years 2001 through 2005 to $75 million for fiscal years 2007 through 2011. According to the Department of Justice, Massachusetts received Section 102 grants in fiscal year 2004 totaling $1,648,863 and in fiscal year 2005 totaling $1,163,097.

Lawmakers in Massachusetts surely would not turn back federal financial assistance to for women who have been victimized by rape and violence simply because they do not believe that survivors of sexual assault should be denied information about the HIV status of their attacker.

Aside from the financial incentives, there are health incentives to assisting survivors of rape. As a physician, I can attest that HIV testing of the alleged is beneficial medically for both the victim's physical and psychological well-being.

The American Medical Association supports this policy because "early knowledge that a defendant is HIV infected would allow the victim to gain access to the ever growing arsenal of new HIV treatment options. In addition, knowing that the defendant was HIV infected would help the victim avoid contact which might put others at risk of infection."

As you know, treatment options are available for early detection. However, because of the toxicity and long-term side effects, these drugs should not be administered without knowing if HIV exposure has occurred. Victims can not rely solely on testing themselves because it can take weeks, sometimes, months, before HIV antibodies can be detected. Therefore, testing the assailant is the only timely manner in which to determine if someone has been exposed to HIV.

Your proposal would also broaden the scope to all STDs, which makes good medical sense since HIV/AIDS, while perhaps the most deadly, is not the only health threat to those who have been raped. There are more than 25 significant STDs, many of which most Americans have never even heard of, such as human papillomavirus (HPV) which is the cause of nearly all cervical cancer.

For these reasons, it is very disappointing to learn there is opposition to your proposal. It seems cruel and inhumane to deny such vitally important information to a woman or child who has survived sexual assault. Claims that providing this information to victims would compromise the "privacy" of the perpetrator are also quite shocking. Exactly whose rights are being protected by denying a victim of sexual assault the right to know if she has been exposed to the deadly AIDS virus when she was raped? If sufficient evidence exists to arrest and jail a rape suspect, the victim should have the right to request that the suspect be tested for HIV. In some circumstances, rape defendants have actually used HIV status information as a plea bargaining tool to reduce their sentences. The health of a rape victim should not be a bargaining tool to lesson the sentence of a sexual predator.

I have attached a copy of the relevant section of the law for your information.

Thank you again for your efforts on behalf of rape survivors. If I can be of any further assistance, please feel free to contact me or Jane Treat of my staff.

Sincerely,

Tom A. Coburn, M.D.
U.S. Senator

Attachment

○